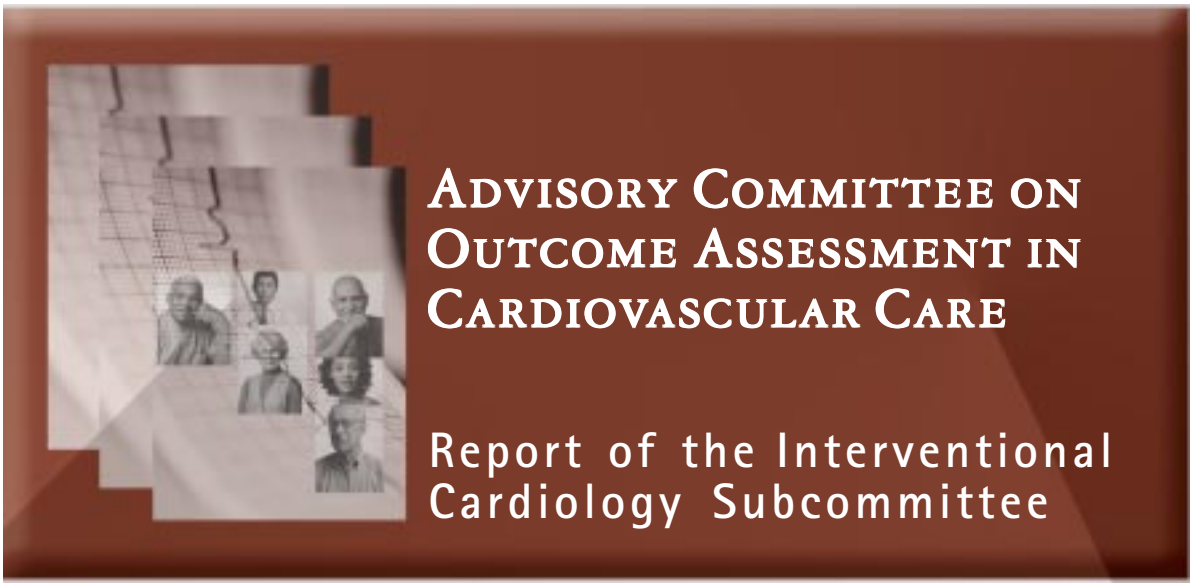

Advisory Committee on Outcome Assessment in Cardiovascular Care

Report of the Interventional Cardiology Subcommittee

David O. Williams, M.D.
Chairman
Interventional Cardiology Subcommittee

June 2003

MHCC
MARYLAND HEALTH CARE COMMISSION

Donald E. Wilson, M.D., MACP
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Advisory Committee on Outcome Assessment in Cardiovascular Care

Report of the Interventional Cardiology Subcommittee

MHCC MARYLAND HEALTH CARE COMMISSION
Division of Health Resources

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EXECUTIVE SUMMARY

Improvements in the technique of angioplasty coupled with expanded indications have increased the number of patients receiving this therapy over the past decade. Maryland hospitals performed almost 12,000 percutaneous coronary intervention (PCI) or angioplasty cases in 2002. There are generally two types of angioplasty procedures. While the large majority of angioplasty procedures are performed as elective procedures, angioplasty is also used as a primary means of urgent revascularization in the treatment of certain patients with acute ST-segment elevation myocardial infarction (MI). When angioplasty is used to treat certain acute MI patients, rather than thrombolytic therapy, the procedure is referred to as primary angioplasty.

The Subcommittee on Interventional Cardiology was formed to assist the Advisory Committee on Outcome Assessment in Cardiovascular Care in reviewing key State health planning and regulatory policies regarding PCI: the limited exemption policy permitting hospitals without on-site cardiac surgery backup to perform primary angioplasty for patients with acute ST-segment elevation MI under the protocols of the C-PORT project; the requirement for on-site cardiac surgical backup for elective PCI; the appropriateness of considering a pilot research project to study the safety and efficacy of elective angioplasty without on-site cardiac surgery backup; and, the recommended minimum utilization threshold for elective angioplasty. The 26-member Subcommittee on Interventional Cardiology, chaired by David O. Williams, M.D., met five times between September 2002-April 2003. The findings and recommendations of the subcommittee are summarized below.

ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

- ### PRE-HOSPITAL MANAGEMENT OF ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

The Maryland Institute for Emergency Medical Services (MIEMSS) should develop and implement a protocol that will triage appropriate acute MI patients to a primary angioplasty center. A patient who meets the triage category of the protocol should be transported to a primary angioplasty center capable of offering interventional cardiology services rather than the "closest" hospital, provided the time to treatment is not significantly increased. Provided that the time to treatment is not increased, the triage should be directed to the "closest" PCI hospital with cardiac surgery backup on-site.

- ### HOSPITAL MANAGEMENT OF ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

The superiority of primary PCI when compared to thrombolytic therapy for the treatment of acute ST-segment elevation MI has been demonstrated in a large number of studies. The Subcommittee on Interventional Cardiology believes that the available evidence suggests that when possible a reperfusion strategy of coronary intervention is preferable to thrombolytic therapy for patients with acute ST-segment elevation MI. Given the safety and effectiveness of

primary PCI for this group of patients, the subcommittee developed recommendations regarding: institutional, physician, and program development requirements for a primary angioplasty center program; minimum and optimal annual volume of procedures for a primary angioplasty program; patient groups suitable for primary angioplasty in settings without on-site cardiac surgery; and process and outcome measures for on-going quality assessment.

For all programs, it is recommended that primary PCI be available 24 hours per day, seven days per week. This recommendation reflects several considerations. Because medical research has established that primary angioplasty is the preferred approach for treating patients with acute ST-segment elevation MI, it is important that this reperfusion strategy be routinely available. Of equal importance, to ensure optimal patient outcomes, is the need to provide primary PCI on a timely basis, preferably within a door-to-balloon time of 120 minutes or less. The emergent nature of acute ST-segment elevation MI patients combined with the need to provide this intervention rapidly requires hospitals providing primary PCI to have in place a detailed logistics plan involving the emergency department, catheterization laboratory, and CCU that can ensure the availability of this service on a 24/7 basis. As the pre-hospital management component for acute ST-segment elevation MI patients is refined and implemented in Maryland, it is also important to consider resource availability from a system of care perspective. For areas of the state with more than one primary PCI facility, it may be possible to ensure the availability of primary angioplasty on a 24/7 basis with a rotating on-call schedule among institutions.

- INSTITUTIONAL, PHYSICIAN, AND PROGRAM DEVELOPMENT REQUIREMENTS FOR A PRIMARY ANGIOPLASTY PROGRAM

The subcommittee believes that the recommended requirements for institutional and physician resources should apply to all programs designated as primary angioplasty centers. In addition, for the initiation of a new primary angioplasty center program, a hospital should complete a program development phase that establishes standards, trains staff, develops detailed logistics, and establishes a quality and error management system.

Institutional Resources

- All institutions should provide primary PCI as routine, treatment of choice for all appropriate acute MI patients 24 hours per day, seven days per week.
- All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients.
- All institutions should have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.
- All institutions should have a written commitment by hospital administration signed by the hospital president to support the program.
- All institutions should design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.

- For hospitals without on-site cardiac surgery there must be a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery; and a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

Physician Resources

- Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year.
- Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MI's during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.
- Physicians who perform primary PCI should agree to participate in an on-call schedule.
- Physicians who perform primary PCI should meet the credentialing criteria for the institution.

Initiation of a New Primary Angioplasty Center Program

- The Maryland Health Care Commission should establish an application process to review requests submitted by hospitals seeking approval to provide primary PCI services without on-site cardiac surgery services.
- All institutions should demonstrate that they have a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MI's annually.
- Because primary PCI is a strategy of care involving a team of health care professionals in multiple care areas, all institutions should begin providing this service only after completing a development program that attends to setting of standards, training of staff, development of logistics and implementation of a formal quality and error management program. The application submitted to the Commission should describe in detail how the hospital proposes to undertake and complete a development program, which may include collaboration with an established primary PCI program.

➢ Relationship Between Volume of Primary Angioplasty Procedures and Outcome

While limited data are now available on the relationship between volume of procedures and outcome, the subcommittee believes that under ideal circumstances the benefits of primary PCI are likely best achieved when a minimum of 49 primary PCI cases are performed. Assuming that as few as 80 percent of potential cases are taken to the catheterization laboratory as recommended in the earlier discussion regarding Institutional

Resources and adjusting that number to reflect cases likely to undergo primary PCI, an institution would require a minimum of at least 85-90 acute ST-segment elevation MI's annually to ensure that 49-52 primary angioplasty procedures are performed. A program performing at least 49 cases annually, or approximately one case per week, is more likely to have developed the clinical expertise and operational pathways for timely and effective reperfusion of acutely ill patients.

If, however, rapid access to a program doing 49 cases is not available, then a site performing 36 or more cases/year is acceptable. An institution would require a minimum of at least 60-65 acute ST-segment elevation MI's annually to ensure that 35-37 primary angioplasty procedures are performed. This approach acknowledges important regional differences in access to primary PCI services. The lower volume standard should only be considered in areas of the state where access to a high volume program is not readily available. The optimal and minimum recommended volume guidelines for primary PCI should be reevaluated by the Commission as additional data becomes available on the relationship between volume of procedures and outcome.

➢ Patient Groups Suitable for Primary Angioplasty in Settings without On-Site Cardiac Surgery

The Subcommittee on Interventional Cardiology believes that the following types of patients can be considered for emergency PCI in settings without on-site cardiac surgery:

- ST-segment elevation MI (or new LBBB or ST-depression V1-V2 compatible with true posterior infarction) that are thrombolytic eligible or thrombolytic ineligible.
- When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, either because the patient is too unstable or because the temporal delay will result in worse outcomes.
- Patients for whom the primary PCI system was not initially available, who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of all cases.

➢ Process and Outcome Measures for On-Going Quality Assessment

Monitoring of the outcomes of care for patients presenting with ST-elevation MI will facilitate on-going quality improvement efforts and provide the opportunity to measure program compliance, safety, and effectiveness. This requires that a uniform data set be developed, collected, and analyzed from all hospitals in Maryland offering primary PCI services. This data set should build upon the elements collected in the C-PORT project.

ELECTIVE PERCUTANEOUS CORONARY INTERVENTION

The current ACC/AHA national guidelines for percutaneous coronary intervention (PCI) recommend that hospitals performing elective PCI have cardiac surgery services available on-site. At institutions without on-site cardiac surgical backup, the ACC/AHA classifies elective angioplasty as Class III meaning there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful. While the limited research conducted has found that it is feasible to perform elective procedures in hospitals without cardiac surgical backup on-site, the small sample of patients studied restricts the extent to which results can reasonably support modifying current planning policies governing the organization of elective PCI services. There has been no clinical trial directly comparing the outcomes of elective PCI performed in hospitals with on-site cardiac surgery with the outcomes of elective PCI performed in hospitals without on-site cardiac surgery. Moreover, methods for identifying those patients who might be best suited for elective PCI in the absence of on-site surgical backup have not been described or validated.

Given the limited body of evidence now available, the Interventional Cardiology Subcommittee believes that Maryland should continue to require that hospitals providing elective angioplasty services have cardiac surgical services on-site. This policy direction, which should continue to be reviewed periodically, should remain in place until clinical evidence confirms the efficacy and safety of elective angioplasty without on-site cardiac surgery backup.

PILOT PROJECT STUDY ON THE NEED FOR ON-SITE CARDIAC SURGICAL BACKUP FOR ELECTIVE PCI

- PILOT PROJECT STUDY TO ASSESS APPROPRIATENESS OF MODIFYING CURRENT POLICY REGARDING AVAILABILITY OF ON-SITE CARDIAC SURGERY FOR CERTAIN GROUPS OF ELECTIVE ANGIOPLASTY PATIENTS

In discussing whether Maryland should support research concerning the need for on-site surgical backup for elective PCI, the Subcommittee on Interventional Cardiology considered a number of issues. While the ability to provide primary angioplasty offered the potential of some clinical benefit to acute MI patients, there is no similar clinical benefit likely with respect to elective cases. On the other hand, the subcommittee recognized the potential benefit to rural hospitals that want to provide primary angioplasty of being able to strengthen program volumes by offering elective procedures. Moreover, the subcommittee recognized the potential value of enhanced convenience for patients, families, and physicians.

Acknowledging there is no clinical benefit for elective patients undergoing angioplasty without on-site surgery, the subcommittee recognizes that the question of the need for on-site cardiac surgical backup for elective angioplasty procedures is the subject of considerable national debate. Given the likelihood that this debate will continue, it is important to consider whether Maryland hospitals should participate in studying the issue given experience with the C-PORT study. Given these considerations, the Interventional Cardiology Subcommittee believes that it would be appropriate for the Maryland Health Care Commission to consider supporting a waiver for a well-designed, peer reviewed research proposal to study the safety of elective PCI

without on-site cardiac surgery. This research proposal must be capable answering questions regarding the need for on-site cardiac surgical backup for elective PCI using accepted principles of scientific investigation. Hospitals wishing to participate in this research proposal could apply to the Commission for this waiver.

- CONSIDERATIONS REGARDING THE DESIGN AND IMPLEMENTATION OF AN ELECTIVE PCI PILOT PROJECT STUDY

The Interventional Cardiology Subcommittee believes that a research proposal to study elective PCI without on-site cardiac surgery must, at a minimum, include the following components: (1) detailed description of the research design and methods; (2) protocol for including patients in the elective PCI research study; (3) need for institutional review board review; (4) criteria for participating hospital sites and physicians (including minimum volume standards for the practitioner and institution); (5) data collection and management plan; (6) timetable for initiating and completing the study; and (7) source and amount of funding necessary to conduct the research study.

The subcommittee also recommends that the Maryland Health Care Commission appoint an advisory committee to review and provide advice on any research proposal submitted to the Commission to study elective angioplasty without on-site cardiac surgery backup. In addition, the Commission should establish an advisory committee to assist in interpreting the results of this and/or other research on the safety of elective PCI without on-site cardiac surgery and to advise the Commission on the appropriateness of modifying State health planning policy governing the requirement to have cardiac surgical services on-site for elective angioplasty. The subcommittee also recommends that the Commission analyze the system impact, including access, cost, and quality implications, of elective angioplasty being performed in hospitals without on-site cardiac surgery.

VOLUME –QUALITY RELATIONSHIP FOR ELECTIVE ANGIOPLASTY

The recently updated ACC/AHA national guidelines recommend a minimum institutional volume of 200 to 400 procedures annually and an optimal institutional volume of more than 400 procedures annually. Those current guidelines recommend that PCI procedures be performed by higher volume operators ($\geq$ 75 cases annually) with advanced technical skills (e.g., subspecialty certification) at well-equipped institutions with experienced support staff performing at least 400 procedures annually.

Higher volume PCI programs have been shown to experience lower mortality rates and lower risk of emergency CABG surgery. Given these findings, the subcommittee believes that PCI programs should perform a minimum of 200-400 procedures annually. Consistent with ACC/AHA recommendations, the subcommittee concludes that for optimal patient outcome an institutional volume of more than 400 PCI procedures should be performed annually.

I. INTRODUCTION

Background

Improvements in the technique of angioplasty coupled with expanded indications have increased the number of patients receiving this therapy over the past decade. Maryland hospitals performed almost 12,000 percutaneous coronary intervention (PCI) or angioplasty cases in 2002. There are generally two types of angioplasty procedures. While the large majority of angioplasty procedures are performed as elective procedures, angioplasty is also used as a primary means of urgent revascularization in the treatment of certain patients with acute ST-segment elevation MI. When angioplasty is used to treat certain acute MI patients, rather than thrombolytic therapy, the procedure is referred to as primary angioplasty.

The Subcommittee on Interventional Cardiology was formed to assist the Advisory Committee on Outcome Assessment in Cardiovascular Care in reviewing key State health planning and regulatory policies regarding PCI. These policies include the requirement for on-site cardiac surgical backup for primary and elective PCI, whether the Commission should consider a pilot research project to study the safety and efficacy of elective angioplasty without on-site cardiac surgery backup, and the recommended minimum utilization threshold for elective angioplasty.

The *State Health Plan: Specialized Health Care Services-Cardiac Surgery and Therapeutic Catheterization Services (COMAR 10.24.17*), effective May 2001, requires that coronary angioplasty services be provided in hospitals with cardiac surgery capabilities. This policy, which reflects the advice of Maryland cardiologists and cardiac surgeons as well as guidelines recommended by medical professional groups, states:

> *Policy 5.0: Percutaneous transluminal coronary angioplasty (PTCA) procedures should only be performed in hospitals with on-site cardiac surgical backup.*

To assess the relative benefits of primary angioplasty versus thrombolytic therapy for the treatment of acute MI, the former Health Resources Planning Commission, a predecessor agency to the Maryland Health Care Commission, approved an exemption from this State Health Plan policy requiring hospitals performing angioplasty to have on-site cardiac surgical backup for the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) project. This exemption, which became effective in January 1996, permits Maryland hospitals participating under the C-PORT study protocol to perform angioplasty without on-site cardiac surgical backup. The exemption for the Atlantic C-PORT project has been extended since that time and the State Health Plan adopted by the Commission in 2001 includes the following policy statement:

> *Policy 5.1: The Commission should maintain the limited exemption policy permitting hospitals without on-site cardiac surgery backup to perform primary angioplasty under the protocols of the C-PORT project.*

Given the Maryland experience with primary angioplasty, the charge to the Subcommittee on Interventional Cardiology included a detailed review of data from the C-PORT

project and other medical research to provide advice on the appropriateness of modifying the State Health Plan policy governing the co-location of PCI and cardiac surgery services for the treatment of patients with acute ST-segment elevation MI.

Whether current health planning policy should be modified to permit Maryland hospitals to participate in a study to assess the safety of performing elective angioplasty without on-site cardiac surgery was another issue considered by the subcommittee. With on-going technical improvements in coronary angioplasty procedures, it is important to review policies governing the requirement for on-site cardiac surgical backup for elective angioplasty cases. The current State Health Plan contains a policy designed to study the safety and efficacy of elective angioplasty in hospitals without on-site cardiac surgery backup:

> *Policy 5.2: The Commission should consider a pilot project to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients. This pilot project should be designed and implemented as a component of the Advisory Committee on Outcome Assessment in Cardiovascular Care.*

The volume-quality relationship for elective PCI was the final issue considered by the Subcommittee on Interventional Cardiology. To promote effective planning for specialized cardiac care services and ensure quality care, the Commission established the following policy governing minimum utilization levels for angioplasty services in the State Health Plan:

> *Policy 1.4: There should be a minimum of 200 percutaneous transluminal coronary angioplasty procedures performed annually in any institution in which elective angioplasty procedures are performed.*

Composition of the Subcommittee

The Subcommittee on Interventional Cardiology includes 26 members representing the disciplines of cardiology, cardiac surgery, planning, and emergency medical services. Figure 1 provides a list of Interventional Cardiology Subcommittee members. The subcommittee is chaired by David O. Williams, M.D. Dr. Williams is Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital in Providence, Rhode Island. He is a Professor of Medicine at the Brown University School of Medicine and a Member of the Cardiac Care Advisory Committee for the Rhode Island State Department of Health. Dr. Williams served on the American College of Cardiology/American Heart Association (ACC/AHA) Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty.

Purpose of the Subcommittee

The Subcommittee on Interventional Cardiology conducted a detailed review of the results of the C-PORT project, the ACC/AHA guidelines, and other relevant studies and developed recommendations on the types of hospitals that should perform primary angioplasty. In addition, the subcommittee reviewed the policy of providing elective angioplasty services only in hospitals with on-site cardiac surgical services. Specifically, the Subcommittee on

Interventional Cardiology studied and developed recommendations to the Steering Committee on four major topics: acute ST-segment elevation MI; elective PCI; pilot project study on the need for on-site cardiac surgical backup for elective PCI; and the volume-quality relationship in elective PCI. The questions considered by the subcommittee for each of these four topic areas were as follows:

Acute ST-Segment Elevation Myocardial Infarction

- *How do outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery compare with outcomes in hospitals with on-site surgery?*
- *What institutional resources are required for a primary angioplasty program? What are the program development requirements for a primary angioplasty program?*
- *Is there a relationship between volume of primary angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?*
- *Which patient groups are suitable for primary angioplasty in settings without on-site cardiac surgery?*
- *What process and outcome measures should be used for on-going quality assessment?*

Elective Percutaneous Coronary Intervention

- *Is there evidence that current policy restricts availability of elective angioplasty services to Maryland patients?*
- *How do outcomes of elective angioplasty performed in hospitals without on-site cardiac surgery compare with the outcomes of elective angioplasty performed in hospitals with cardiac surgery?*

Pilot Project Study on the Need for On-Site Cardiac Surgical Backup for Elective Percutaneous Coronary Intervention

- *Should the Commission consider a pilot project study to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients?*
- *How should this pilot project be designed and implemented? What would be the resource and program development requirements for a participating hospital? What process and outcome measures should be used for on-going quality assessment? Which patient groups would be suitable for inclusion in a pilot program study of elective angioplasty?*

Volume-Quality Relationship in Elective Percutaneous Coronary Intervention

- *Is there a relationship between volume of elective angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?*

The Subcommittee on Interventional Cardiology held a total of five meetings from September 2002 to April 2003. Meetings of the subcommittee were announced and open to the public. At its first meeting on September 4, 2002, the subcommittee members discussed the charge, structure, and timetable as well as a proposed work plan and process. The second meeting was held on October 16, 2002. The subcommittee had a presentation from Thomas

Aversano, M.D. regarding the experience of hospitals participating in the C-PORT trial and registry at that meeting. On February 19, 2003, the subcommittee began discussing the questions posed in its charge regarding primary angioplasty. At the March 10, 2003 meeting, the subcommittee reviewed a draft document summarizing their findings and recommendations regarding acute ST-segment elevation MI and discussed a series of questions on elective PCI. The final subcommittee meeting was held on April 14, 2003. At that meeting, the subcommittee reviewed and suggested changes to the findings and recommendations regarding acute ST-segment elevation MI and elective PCI.

Report Organization

Following this Introduction, the report provides an overview and background information on the Advisory Committee on Outcome Assessment in Cardiovascular Care. In Section III of the report, the findings and recommendations of the Subcommittee on Interventional Cardiology are organized in four major areas corresponding to the questions posed in the subcommittee's charge from the Steering Committee: Acute ST-Segment Elevation MI; Elective PCI; Pilot Project Study on the Need for On-Site Cardiac Surgical Backup for Elective PCI; and Volume-Quality Relationship for Elective PCI. The Appendices to the Report of the Interventional Cardiology Subcommittee include a summary of recommended requirements for primary PCI programs in hospitals with and without on-site cardiac surgery and summary minutes of the five subcommittee meetings.

Figure 1

Advisory Committee on Outcome Assessment in Cardiovascular Care

INTERVENTIONAL CARDIOLOGY SUBCOMMITTEE

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(Continued on next page)

Figure 1 (Continued)

Advisory Committee on Outcome Assessment in Cardiovascular Care

INTERVENTIONAL CARDIOLOGY SUBCOMMITTEE

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II. ADVISORY COMMITTEE ON OUTCOME ASSESSMENT IN CARDIOVASCULAR CARE

Purpose of the Advisory Committee

The updated Maryland State Health Plan chapter, COMAR 10.24.17, governing cardiac surgery and therapeutic catheterization services adopted by the Maryland Health Care Commission became effective in May 2001. In preparing this plan, the Commission recognized the need to establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to promote the development of a Maryland model for continuous quality improvement.

The purpose of the Advisory Committee on Outcome Assessment in Cardiovascular Care is to study and develop recommendations to the Commission on establishing an on-going, statewide quality improvement program in cardiovascular care. The goals of this effort are to identify baseline indicators to measure current performance, design an approach for continuous quality improvement, and evaluate options for funding a statewide quality improvement effort. In addition to targeting performance improvement for care currently provided, the Commission is interested in better understanding how the organization of cardiac services impacts quality of care and access considerations. Key tasks involved in this project are outlined below:

- Identify quality measures and risk adjustment methods and develop recommendations on the structure and content of a Maryland Cardiovascular Care Data Reporting System designed to support outcome assessment;
- Study available models for quality improvement in cardiovascular care, focusing initially on cardiac surgery and coronary angioplasty services, and develop recommendations on the appropriate governance, organizational structure, staffing, and funding for an on-going outcome assessment process for cardiovascular care in Maryland;
- Develop a research agenda to advance the understanding of how cardiac care services should be organized to improve outcomes, including, but not limited to, developing an evidence-based approach to reviewing policies governing the location of primary and elective angioplasty services; and
- Identify strategies for developing a statewide inter-hospital transport system for specialized cardiac care services and recommend actions that public and private sector organizations should take to implement an inter-hospital transport system.

Organizational Structure

In early 2002, the Commission took steps to organize and appoint the Advisory Committee on Outcome Assessment in Cardiovascular Care. In order to get broad participation in the process, and to focus available expertise in specific areas, the Commission structured the Advisory Committee to include a Steering Committee and four subcommittees (refer to Figure 2). Steering Committee members were appointed by Donald E. Wilson, M.D., MACP, Chairman of the Maryland Health Care Commission, after considering nominations received from a wide range of organizations, including hospitals, state and national professional associations, state

government, and health care policy research organizations. The Steering Committee is chaired by James Scheuer, M.D., a Professor of Medicine and University Chairman Emeritus at the Albert Einstein College of Medicine/Montefiore Medical Center in New York. Each subcommittee includes members from the Steering Committee as well as other interested individuals. Members of the Steering Committee have been appointed to chair each subcommittee. Recommendations developed by each subcommittee are submitted to the Steering Committee and the Steering Committee reports directly to the Commission. The Commission sought participants from a wide range of organizations, including the Maryland Department of Health and Mental Hygiene, the Maryland Institute for Emergency Medical Services Systems, Maryland acute care hospitals, and state and national professional associations, in appointing subcommittee members. The four subcommittees established to assist the Steering Committee include:

- *Subcommittee on Quality Measurement and Data Reporting*

This subcommittee studied available models for quality improvement in cardiovascular care and developed recommendations to the Steering Committee on the approach that should be used in Maryland.

- *Subcommittee on Interventional Cardiology*

This subcommittee conducted a detailed review of the results of the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) project and developed recommendations on the types of hospitals that should perform primary angioplasty. In addition, the subcommittee reviewed the policy of providing elective angioplasty services only in hospitals with on-site cardiac surgical services and the recommended minimum utilization standard for elective angioplasty.

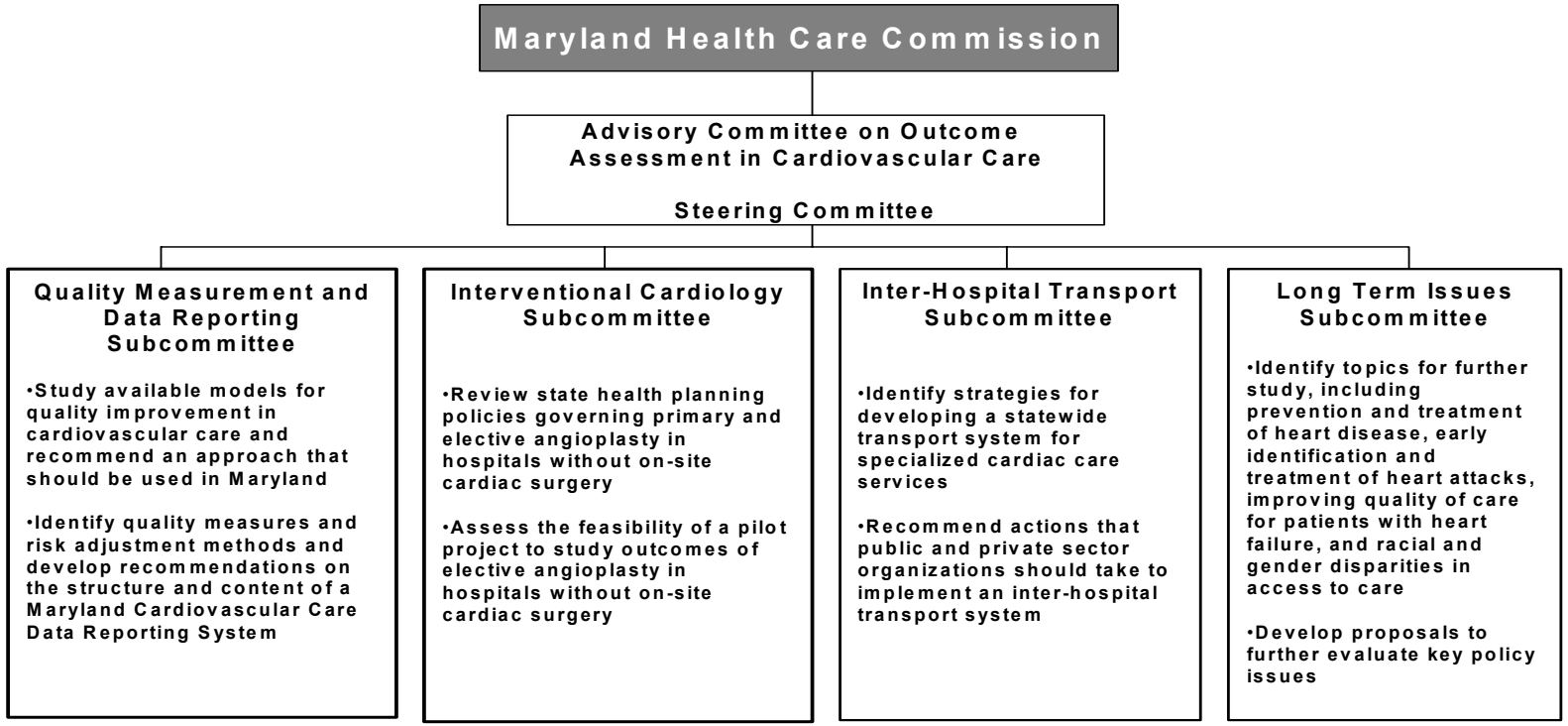
- *Subcommittee on Inter-Hospital Transport*

The Subcommittee on Inter-Hospital Transport studied strategies for improving the transport of cardiac patients between hospitals. The subcommittee identified potential strategies for developing a statewide approach to the inter-hospital transport system for specialized cardiac care services and recommended actions that public and private sector organizations should take to strengthen the inter-hospital transport system.

- *Subcommittee on Long Term Issues*

The focus of this subcommittee is on identifying topics for further study, developing proposals to further evaluate key policy issues, and developing a long-range, evidence-based approach for assessing the impact of changes in cardiovascular services. This subcommittee considered the feasibility and advisability of developing programs that address other issues in cardiovascular health and disease, such as screening, primary and secondary prevention, hypertension, and diabetes care.

Figure 2 **Organizational Structure: Advisory Committee on Outcome Assessment in Cardiovascular Care**



III. FINDINGS AND RECOMMENDATIONS OF THE INTERVENTIONAL CARDIOLOGY SUBCOMMITTEE

ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

The *Maryland State Health Plan: Specialized Health Care Services-Cardiac Surgery and Therapeutic Catheterization Services* includes procedures for exempting certain research projects from the policy requiring co-location of cardiac surgery and angioplasty services. Under these exemption procedures, the former Maryland Health Resources Planning Commission approved a request from Thomas Aversano, M.D. of the Johns Hopkins Medical Institutions to permit selected Maryland hospitals participating in the C-PORT clinical trial to perform primary angioplasty under the protocols of this research project.

Hospitals participating in this research project may perform angioplasty as a primary means of urgent revascularization in the treatment of patients with acute ST-segment MI without the requirement for on-site cardiac surgical backup. This exemption was originally granted for two years from an effective date of January 15, 1996, and has been extended at the request of Dr. Aversano since that time. In 2002, the Maryland Health Care Commission extended the exemption for the C-PORT project through June 2003. [1]From 1996 to 1999, the C-PORT project enrolled patients in a randomized, clinical trial. In its second phase, which began in August 1999, the C-PORT project is functioning as a registry.

Although there remain important questions on the role of primary angioplasty in treating acute MI, this therapy has gained widespread acceptance among cardiologists as the preferred approach for treating acute ST-segment elevation MI when it can be performed rapidly and in the right environment. The Subcommittee on Interventional Cardiology reviewed data from the C-PORT project and other medical research to evaluate the most effective strategies for improving the system of care for patients with acute ST-segment elevation MI. While the primary goal of the subcommittee was to advise the Commission on the appropriateness of modifying the State Health Plan policy governing the co-location of PCI and cardiac surgery services for the treatment of patients with acute ST-segment elevation MI, the subcommittee also considered related issues including pre-hospital management of patients with acute MI. The charge to the Subcommittee on Interventional Cardiology included a series of questions regarding primary PCI. The subcommittee's analysis and recommendations with respect to these questions is provided in this document. The subcommittee recognizes that these findings are based on currently available data. As new data are collected, the subcommittee recommends that these findings be reviewed and modified as appropriate.

[1] In correspondence dated June 24, 2003 to Thomas Aversano, M.D., the Commission's Executive Director, Barbara G. McLean, extended the waiver granted to the C-PORT Project to permit the Commission to act on an updated State Health Plan reflecting the findings and recommendations of the Advisory Committee on Outcome Assessment in Cardiovascular Care.

Pre-Hospital Management of Acute ST-Segment Elevation Myocardial Infarction

The Maryland Institute for Emergency Medical Services (MIEMSS) should develop and implement a protocol that will triage appropriate acute MI patients to a primary angioplasty center. Improvements in the technology of electrocardiographic equipment have made it possible for pre-hospital care providers to obtain and transmit 12-lead ECGs. Because this technology offers the benefit of decreasing the time between onset of an MI and definitive treatment, the subcommittee believes that the mobile electrocardiogram is a key element of any plan to improve the system of care for acute ST-segment elevation MI. A patient who meets the triage category of the protocol should be transported to a primary angioplasty center capable of offering interventional cardiology services rather than the "closest" hospital, provided the time to treatment is not significantly increased. Provided that the time to treatment is not increased, the triage should be directed to the "closest" PCI hospital with cardiac surgery backup on-site.

Hospital Management of Acute ST-Segment Elevation Myocardial Infarction

The superiority of primary PCI when compared to thrombolytic therapy for the treatment of acute ST-segment elevation MI has been demonstrated in a large number of studies.[2] The Subcommittee on Interventional Cardiology believes that the available evidence suggests that when possible a reperfusion strategy of coronary intervention is preferable to thrombolytic therapy for patients with acute ST-segment elevation MI. Given the safety and effectiveness of primary PCI for this group of patients, the subcommittee considered a number of questions related to the future organization and delivery of primary PCI services in Maryland.

1. Comparison of Primary Angioplasty Outcomes in Hospitals With and Without On-Site Cardiac Surgery

The Subcommittee on Interventional Cardiology examined available data comparing the outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery with outcomes in hospitals with on-site surgery. Some registry studies have suggested that programs without on-site cardiac surgery can safely and effectively provide primary angioplasty in a high-risk population and that outcomes might be similar to those reported from high volume surgical centers.[3] While available research is helpful, there is no controlled randomized trial that addresses this comparison. The subcommittee

[2] Keeley, EC, Boura, JA, and Grines, CL. Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials. *The Lancet*. Vol. 361, January 4, 2003:13-20.

[3] Wharton, TP Jr. Primary angioplasty at hospitals with off-site cardiac surgical backup: draft of response to Question 1 of the April 2002 document of the Subcommittee on Interventional Cardiology, Advisory Committee on Outcome Assessment in Cardiovascular Care, p. 2-3.

felt that available data are insufficient to answer this question with confidence. Future clinical trials may investigate this subject with results that influence the strategy for managing these patients.

2. Institutional, Physician, and Program Development Requirements for a Primary Angioplasty Program

The Subcommittee on Interventional Cardiology reviewed the recommendations governing operator and institutional requirements for a primary angioplasty program developed by: the ACC/AHA Task Force on Practice Guidelines[4]; Wharton and colleagues; Thomas Aversano, M.D., Principal Investigator for C-PORT; and other relevant publications. Based on this review, the subcommittee believes that the institutional and physician resource requirements should apply to all programs designated as primary angioplasty centers. In addition, for the initiation of a new PCI program, a hospital should complete a program development phase that establishes standards, trains staff, develops detailed logistics, and establishes a quality and error management system.

For all programs, it is recommended that primary PCI be available 24 hours per day, seven days per week. This recommendation reflects several considerations. Because medical research has established that primary angioplasty is the preferred approach for treating patients with acute ST-segment elevation MI, it is important that this reperfusion strategy be routinely available. Of equal importance, to ensure optimal patient outcomes, is the need to provide primary PCI on a timely basis, preferably within a door-to-balloon time of 120 minutes or less. The emergent nature of acute ST-segment elevation MI patients combined with the need to provide this intervention rapidly requires hospitals providing primary PCI to have in place a detailed logistics plan involving the emergency department, catheterization laboratory, and CCU that can ensure the availability of this service on a 24/7 basis. As the pre-hospital management component for acute ST-segment elevation MI patients is refined and implemented in Maryland, it is also important to consider resource availability from a system of care perspective. For areas of the state with more than one primary PCI facility, it may be possible to ensure the availability of primary angioplasty on a 24/7 basis with a rotating on-call schedule among institutions.

The recommended institutional, physician, and program development requirements are as follows (also refer to Appendix A.):

[4] Smith SC, Jr., Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:1-66.

a. Institutional Resources

(1) All institutions should provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week.

(2) All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients.

(3) All institutions should have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.

(4) All institutions should have a written commitment by hospital administration signed by the hospital president to support the program, and be required to:

(i) identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges;

(ii) develop a formal, regularly scheduled (meetings every other month) interventional case review that requires attendance by a critical mass of interventionalists and other physicians, nurses, and technicians who care for primary PCI patients; and

(iii) create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes at a minimum the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

(5) All institutions should design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.

For hospitals without on-site cardiac surgery programs:

(6) There must be a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.

(7) There must be a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.

b. Physician Resources

(1) Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year.

(2) Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MI's during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.

(3) Physicians who perform primary PCI should agree to participate in an on-call schedule.

(4) Physicians who perform primary PCI should meet the credentialing criteria for the institution.

c. Initiation of a New Primary Angioplasty Center Program

(1) The Maryland Health Care Commission should establish an application process to review requests submitted by hospitals seeking approval to provide primary PCI services without on-site cardiac surgery services.

(2) All institutions should demonstrate that they have a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MI's annually.

(3) Because primary PCI is a strategy of care involving a team of health care professionals in multiple care areas, all institutions should begin providing this service only after completing a development program that attends to setting of standards, training of staff, development of logistics and implementation of a formal quality and error management program.[5] The application submitted to the Commission should describe in detail how the hospital proposes to undertake and complete a development program, which may include collaboration with an established primary PCI program. The development program should contain the following major components:

[5] Aversano, T, Aversano, LT, Passamani, E, Knatterud, GL, Terrin, ML, Williams, DO, Forman, SA. Thrombolytic therapy vs. primary percutaneous coronary intervention for myocardial infarction in patients presenting to hospitals without on-site cardiac surgery: a randomized controlled trial. *JAMA*, Vol. 287, No. 15, April 17, 2002, Supplement to the 'Methods' Section. Accessed March 20, 2003 at http://www.cport.org/jama.htm.

(i) The standards contained in the American College of Cardiology and American Heart Association Guidelines for Management of Patients with Acute Myocardial Infarction[6] and Guidelines for Percutaneous Coronary Intervention[7] will be used to guide care provided in primary PCI programs.

(ii) Nursing and technical staff in both the catheterization laboratory and in pre and post-procedure care units will require additional training, including familiarization with angioplasty equipment, commonly used drugs, intra-aortic balloon counterpulsation equipment, and patient transfer to and from the laboratory, and other pre-and post-procedure care issues.

(iii) The logistical issues that need to be addressed in the primary PCI development program include at a minimum: hours of operation, who obtains consent, mechanisms to gather staff, mechanisms to assure availability of staff and catheterization laboratory, plans for recurrent ischemia or infarction, plans to determine the responsible physician during and after primary angioplasty, plans for failed angioplasty, and fall-back plans for primary angioplasty system failure.

(iv) The quality and error management component of the primary angioplasty development program should give special emphasis to minimizing, discovering, reporting, and correcting error in the system of acute MI care.

3. Relationship Between Volume of Primary Angioplasty Procedures and Outcome

Current evidence demonstrates an inverse relationship between the volume of primary angioplasty procedures performed and in-hospital mortality. With respect to the recommended volume of primary PCI cases in hospitals without on-site cardiac surgery, the ACC/AHA guidelines recommend a minimum of 36 procedures per year based on data suggesting that both door to balloon time and in-hospital mortality are significantly

[6] Ryan TJ, Antman EM, Brooks NH, Califf RM, Hillis LD, Hiratzka LF, Rapaport E, Riegel B, Russell Rom Smith EE III, Weaver WD. ACC/AHA guidelines for the management of patients with acute myocardial infarction: 1999 update: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction). www.acc.org. September 1999:1-91.

[7] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:1-66.

lower at hospitals able to perform at this volume level.[8] [9] Assuming that as few as 80 percent of potential cases are taken to the catheterization laboratory as recommended in the earlier discussion regarding Institutional Resources [a. (2)] and adjusting that number to reflect cases likely to undergo primary PCI, an institution would require a minimum of at least 60-65 acute ST-segment elevation MI's annually to ensure that 35-37 primary angioplasty procedures are performed.

Data are also available to suggest that outcomes are better overall for programs performing 49 or more primary PCI cases annually. A study by Magid and colleagues found that high volume primary PCI programs, defined as 49 or more procedures annually, had the lowest mortality when compared to both intermediate and low volume groups.[10] Assuming that as few as 80 percent of potential cases are taken to the catheterization laboratory and adjusting that number for expected actual primary PCI procedures, an institution would require a minimum of 85-90 acute ST-segment elevation MI's annually to ensure an optimal institutional volume of 49-52 primary angioplasty procedures.

Table 1
Relationship Between Annual Acute STEMI Patients and Minimum and Optimal Institutional Volumes of Primary PCI Cases

Relationship Between Annual Acute STEMI Patients and Expected Primary PCI Cases	**Minimum Institutional Volume**	**Optimal Institutional Volume**
	Institutions Performing at Least 36 Primary PCI Procedures Annually	**Institutions Performing ≥ 49 Primary PCI Procedures Annually**
Annual Acute ST-Segment Elevation MI (STEMI) Cases	60-65	85-90
Expected Primary PCI Cases*	35-37	49-52

**NOTE: The number of expected primary PCI cases is estimated based on the following assumptions. First, it is assumed that up to 20% of STEMI patients will not undergo primary PCI because of logistical issues that may limit catheterization laboratory availability. Of the potential candidates for primary PCI, it is also assumed that up to 20% will not be suitable for primary PCI (e.g., greater than 12 hrs. from onset to catheterization laboratory arrival). Finally, approximately 10% of eligible patients will not receive a primary PCI intervention because of anatomic and technical considerations.*

[8] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:21.

[9] Cannon, CP, Gibson, CM, Lambrew CT et al. Relationship of symptom-onset-to-balloon time and door-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction. *JAMA*. 2000; 283:2941-2947.

[10] Magid, DJ, Calonge, BN, Rumsfeld, JS et al. Relation between hospital primary angioplasty volume and mortality for patients with acute MI treated with primary angioplasty vs. thrombolytic therapy. *JAMA*. 2000; 284:3131-3138.

While limited data are now available on the relationship between volume of procedures and outcome, the subcommittee believes that under ideal circumstances the benefits of primary PCI are likely best achieved when a minimum of 49 primary PCI cases are performed. A program performing at least 49 cases annually, or approximately one case per week, is more likely to have developed the clinical expertise and operational pathways for timely and effective reperfusion of acutely ill patients. If, however, rapid access to a program doing 49 cases is not available, then a site performing 36 or more cases/year is acceptable. This approach acknowledges important regional differences in access to primary PCI services. The lower volume standard should only be considered in areas of the state where access to a high volume program is not readily available. The optimal and minimum recommended volume guidelines for primary PCI should be reevaluated by the Commission as additional data becomes available on the relationship between volume of procedures and outcome.

4. Patient Groups Suitable for Primary Angioplasty in Settings without On-Site Cardiac Surgery

The Subcommittee on Interventional Cardiology believes that the following types of patients can be considered for emergency PCI in settings without on-site cardiac surgery:

a. ST-segment elevation myocardial infarction (or new LBBB or ST-depression V1-V2 compatible with true posterior infarction) who are
   - thrombolytic eligible or
   - thrombolytic ineligible.

b. When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

c. Patients for whom the primary PCI system was not initially available, who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of all cases.

5. Process and Outcome Measures for On-Going Quality Assessment

Monitoring of the outcomes of care for patients presenting with ST-segment elevation MI will facilitate on-going quality improvement efforts and provide the opportunity to measure program compliance, safety, and effectiveness. This requires that a uniform data set be developed, collected, and analyzed from all hospitals in Maryland offering primary PCI services. This data set should build upon the elements collected in the C-PORT project.

The subcommittee believes that a plan should be developed for this effort. Included would be data on: patient demographic and clinical characteristics; times of

symptom onset, arrival in the emergency department, arrival in the catheterization lab, catheterization procedure onset and termination, balloon inflation, procedural outcome; complications; need for emergency cardiac surgery; incidence and indication for hospital transfers, adjunctive medical therapies, and clinical outcomes (including in-hospital mortality, stroke, and long-term follow-up).

ELECTIVE PERCUTANEOUS CORONARY INTERVENTION

With the assistance of Maryland cardiologists and cardiac surgeons, the Commission has conducted periodic reviews of the state health planning policy requiring hospitals providing elective PCI services to have on-site cardiac surgery. The charge to the Subcommittee on Interventional Cardiology contained a series of questions regarding elective PCI, including whether current health planning policy should be modified to permit hospitals to perform elective angioplasty without on-site cardiac surgery.

1. Availability of Elective Angioplasty Services

During 2002, the nine Maryland hospitals with open heart surgery and PCI programs performed about 12,000 angioplasty procedures. The Interventional Cardiology Subcommittee found no problem with the availability of elective angioplasty services to Maryland patients.

2. Comparison of Elective Angioplasty Outcomes in Hospitals With and Without On-Site Cardiac Surgery

The current ACC/AHA national guidelines for percutaneous coronary intervention (PCI) recommend that hospitals performing elective PCI have cardiac surgery services available on-site.[11] At institutions without on-site cardiac surgical backup, the ACC/AHA classifies elective angioplasty as Class III[12] meaning there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful. Because angioplasty is an evolving technology for treating cardiovascular disease, the ACC/AHA committee has reviewed this policy direction on several occasions over the past 15 years. The current recommendation reaffirming the on-site cardiac surgical backup requirement for elective PCI was completed in March-April 2001 and reflects several important considerations. Those

[11] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:1-66.

[12] The ACC/AHA uses a classification system to summarize the indications for PCI as follows: *Class I*-conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective; *Class II*-conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment (*Class IIa*-weight of the evidence/opinion is in favor or usefulness/efficacy; *Class IIb*-usefulness/efficacy is less well established by evidence/opinion); and *Class III*-conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective, and in some cases may be harmful.

considerations include: the benefit, in terms of better outcomes, of ensuring that high volume interventionalists in high volume programs perform elective PCI; the need for timely management of post-intervention complications; and, the need to ensure the availability of services required for any specialized follow-up care.

Over the past two decades, the growing body of experience with angioplasty combined with improvements in the technology, including coronary stents and antiplatelet drugs, has contributed to increasing the clinical success of the procedure and lowering the incidence of complications requiring emergency coronary artery bypass graft (CABG) surgery. Data reviewed by the ACC/AHA in developing the current PCI guidelines shows that the incidence of emergency CABG surgery has declined from 5.8 percent (1977-1986) to between 0.4 -1.3 percent (1995-1998). With improvements in PCI, cardiac surgical backup has changed from having an operating room and surgical team immediately available on a scheduled standby basis to a next available basis.

To date, however, there have been only a few observational studies addressing the safety of elective PCI at hospitals without on-site cardiac surgery. While the limited research conducted has found that it is feasible to perform elective procedures in hospitals without cardiac surgical backup on-site, the small sample of patients studied restricts the extent to which results can reasonably support modifying current planning policies governing the organization of elective PCI services.[13] [14] There has been no clinical trial directly comparing the outcomes of elective PCI performed in hospitals with on-site cardiac surgery with the outcomes of elective PCI performed in hospitals without on-site cardiac surgery. Moreover, methods for identifying those patients who might be best suited for elective PCI in the absence of on-site surgical backup have not been described or validated.

Given the limited body of evidence now available, the Interventional Cardiology Subcommittee believes that Maryland should continue to require that hospitals providing elective angioplasty services have cardiac surgical services on-site. This policy direction, which should continue to be reviewed periodically, should remain in place until clinical evidence confirms the efficacy and safety of elective angioplasty without on-site cardiac surgery backup.

[13] Klinke, WP and Hui, W. Percutaneous transluminal coronary angioplasty without on-site surgical facilities. *Am J Cardiology*. Vol. 70, December 15, 1992: 1520-1525.
[14] Ting, HH; Garratt, KN; Singh, M et al. Low-risk percutaneous coronary interventions without on-site cardiac surgery: two years' observational experience and followup. *American Heart Journal*. Vol. 145, February 2003:278-284.

PILOT PROJECT STUDY ON THE NEED FOR ON-SITE CARDIAC SURGICAL BACKUP FOR ELECTIVE PCI

1. Pilot Project Study to Assess Appropriateness of Modifying Current Policy Regarding Availability of On-Site Cardiac Surgery for Certain Groups of Elective Angioplasty Patients

For cardiac care services, Maryland has developed planning policies based on clinical evidence from medical research and the expertise and advice of cardiologists and cardiac surgeons. For angioplasty services, where significant advances in technology have increased experience with the procedure over the past decade, the Commission has supported research designed to examine whether primary angioplasty services can be safely provided by hospitals without on-site cardiac surgery programs. In 1996, the Commission approved a waiver from the requirement for on-site cardiac surgical backup to permit a small number of Maryland hospitals to participate in a research study to evaluate the safety and efficacy of providing primary angioplasty in hospitals without on-site cardiac surgery. The data from this study, the C-PORT clinical trial and registry, made an important contribution to the knowledge base concerning primary angioplasty.

In discussing whether Maryland should support research concerning the need for on-site surgical backup for elective PCI, the Subcommittee on Interventional Cardiology considered a number of issues. While the ability to provide primary angioplasty offered the potential of some clinical benefit to acute MI patients, there is no similar clinical benefit likely with respect to elective cases. On the other hand, the subcommittee recognized the potential benefit to rural hospitals that want to provide primary angioplasty of being able to strengthen program volumes by offering elective procedures. Moreover, the subcommittee recognized the potential value of enhanced convenience for patients, families, and physicians.

Acknowledging there is no clinical benefit for elective patients undergoing angioplasty without on-site surgery, the subcommittee recognizes that the question of the need for on-site cardiac surgical backup for elective angioplasty procedures is the subject of considerable national debate. Given the likelihood that this debate will continue, it is important to consider whether Maryland hospitals should participate in studying the issue given experience with the C-PORT study. Given these considerations, the Interventional Cardiology Subcommittee believes that it would be appropriate for the Maryland Health Care Commission to consider supporting a waiver for a well-designed, peer reviewed research proposal to study the safety of elective PCI without on-site cardiac surgery. This research proposal must be capable of answering questions regarding the need for on-site cardiac surgical backup for elective PCI using accepted principles of scientific investigation. Hospitals wishing to participate in this research proposal could apply to the Commission for this waiver.

2. Considerations Regarding the Design and Implementation of an Elective PCI Pilot Project Study

The Interventional Cardiology Subcommittee believes that a research proposal to study elective PCI without on-site cardiac surgery must, at a minimum, include the following components: (1) detailed description of the research design and methods; (2) protocol for including patients in the elective PCI research study; (3) need for institutional review board review; (4) criteria for participating hospital sites and physicians (including minimum volume standards for the practitioner and institution); (5) data collection and management plan; (6) timetable for initiating and completing the study; and (7) source and amount of funding necessary to conduct the research study. The subcommittee also recommends that the Maryland Health Care Commission appoint an advisory committee to review and provide advice on any research proposal submitted to the Commission to study elective angioplasty without on-site cardiac surgery backup. In addition, the Commission should establish an advisory committee to assist in interpreting the results of this and/or other research on the safety of elective PCI without on-site cardiac surgery and to advise the Commission on the appropriateness of modifying State health planning policy governing the requirement to have cardiac surgical services on-site for elective angioplasty. The subcommittee also recommends that the Commission analyze the system impact, including access, cost, and quality implications, of elective angioplasty being performed in hospitals without on-site cardiac surgery.

VOLUME –QUALITY RELATIONSHIP FOR ELECTIVE ANGIOPLASTY

Under the current *Maryland State Health Plan: Specialized Health Care Services-Cardiac Surgery and Therapeutic Catheterization Services,* the minimum volume threshold for angioplasty is 200 procedures annually. This recommendation is based on the minimum volume guidelines published by the ACC/AHA for coronary angioplasty programs in 1993.[15] The recently updated ACC/AHA national guidelines recommend a minimum institutional volume of 200 to 400 procedures annually and an optimal institutional volume of more than 400 procedures annually (Refer to Table 2). Those current guidelines recommend that PCI procedures be performed by higher volume operators (≥ 75 cases annually) with advanced technical skills (e.g., subspecialty certification) at well-equipped institutions with experienced support staff performing at least 400 procedures annually.[16]

Between 1993-2000, nine major studies, using data sources ranging from registries to hospital discharge files, have examined the relationship between the volume of coronary angioplasty procedures and outcome. The outcome measures used by these studies include CABG surgery following a failed angioplasty procedure and/or death. Table 3 summarizes the characteristics and findings of each study. All nine of these studies suggest that hospitals performing higher volumes of coronary angioplasty procedures have fewer complications and/or deaths than low volume hospitals. The results from six of the studies indicate that the appropriate minimum volume benchmark for PCI programs is 400 cases annually. One study, reflecting the experience from New York State, suggests that 600 cases annually should serve as the minimum volume standard for hospital angioplasty programs. While many of the studies were done before the widespread use of stents, the study by McGrath and colleagues examined the relationship between physician and hospital PCI volumes and patient outcomes after stents became routinely used in PCI cases. This study shows that the strong inverse relationship between volume and patient outcomes (i.e., most favorable outcomes were observed at the highest volume centers with the highest volume physicians), as measured by mortality, remains even with recent advances in stent technology that have reduced complications and mortality following PCI.[17]

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[15] Ryan, TJ. Bauman WB. Kennedy JW. et al. Guidelines for Percutaneous Transluminal Coronary Angioplasty: A Report of the American Heart Association/American College of Cardiology Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures. *Circulation*. 1993; 88:2987-3007.

[16] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:1-66.

[17] McGrath, PD; Wennberg, DE; Dickens, JD; Siewers, AE; Lucas, FL; Malenka, DJ; Malenka, DJ; Kellett, MA; Ryan, TJ. Relation between operator and hospital volume and outcomes following percutaneous coronary interventions in the era of the coronary stent. *JAMA*. Volume 284, No.24, December 27, 2000:3139-3144.

Table 2
Recommendations for PCI Institutional and Operator Volume at Centers with On-Site Cardiac Surgery

Operator Volume	Minimum Institutional Volume	Optimal Institutional Volume
	Institutions Performing 200-400 Procedures Annually	**Institutions Performing >400 Procedures Annually**
Low (< 75 procedures annually)	**Class IIb** PCI done by low volume operators (< 75) at low volume centers (200-400)* *(Level of Evidence:C)* *Note: An institution with a volume < 200 procedures/year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer the service.*	**Class IIa** PCI done by low volume operators (< 75) at high volume centers (> 400)* *(Level of Evidence: C)* *Note: Ideally, operators with annual procedure volume < 75 should only work at institutions with an activity level of > 600 procedures/year.*
Acceptable (≥ 75 procedures annually)	**Class IIa** PCI done by operators with acceptable volume (≥ 75) at low volume centers (200-400) *(Level of Evidence: C)*	**Class I** PCI done by operators with acceptable volume (≥ 75) at high volume centers (> 400) *(Level of Evidence: B)*

*Note: Operators who perform <75 procedures/year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume ≥ 150 procedures/year. (For definitions of the ACC/AHA classes refer to Footnote 12 in this document. The weight of evidence in support of the recommendation is as follows: *Level of Evidence A:* Data derived from multiple randomized clinical trials; *Level of Evidence B*: Data derived from a single randomized trial or nonrandomized studies; *Level of Evidence C*: Consensus opinion of experts)

Source: Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Journal of the American College of Cardiology*. Vol. 37, No. 8, June 15, 2001:20.

In summary, the Interventional Cardiology Subcommittee concludes that available data clearly documents the relationship between major complications and annual volume of procedures for elective PCI. Higher volume PCI programs have been shown to experience lower mortality rates and lower risk of emergency CABG surgery. Given these findings, the subcommittee believes that PCI programs should perform a minimum of 200-400 procedures annually. Consistent with ACC/AHA recommendations, the subcommittee concludes that for optimal patient outcome an institutional volume of more than 400 PCI procedures should be performed annually.

Table 3
Findings of Major Studies on the Relationship Between Coronary Angioplasty Program Volumes and Outcomes

Study	Data Source	Year(s) of Data/Total Sample Size	Findings
McGrath, PD; Wennberg, DE; Dickens, JD; Siewers, AE; Lucas, FL; Malenka, DJ; Malenka, DJ; Kellett, MA; Ryan, TJ. Relation between operator and hospital volume and outcomes following percutaneous coronary interventions in the era of the coronary stent. *JAMA*. Volume 284, No.24, December 27, 2000: 3139-3144.	Medicare National Claims History files- Part A (hospital) and Part B (physician) for each hospitalization billed to Medicare	1997 N= 167,208 (1,003 hospitals; 6,534 physicians)	Overall unadjusted rates of CABG during the index hospitalization and 30-day mortality were 1.87% and 3.30%, respectively. After adjustment for case mix, patients treated by low-volume (< 30 Medicare procedures) physicians had an increased risk of CABG vs. patients treated by high-volume (>60 Medicare procedures) physicians (2.25% vs. 1.55%; P<.001), but there was no difference in 30-day mortality rates (3.25% vs. 3.39%; P<.27). Patients treated at low volume (<80 Medicare procedures) centers had an increased risk of 30-day mortality vs. patients treated at high-volume (>160 Medicare procedures) centers (4.29% vs. 3.15%; P<.001), but there was no difference in risk of CABG. In patients who received coronary stents, the CABG rate was 1.20% vs. 2.78% for patients not receiving stents, and the 30-day mortality rate was 2.83% vs. 3.94%. Among patients who received stents, those treated at low-volume centers had an increased risk of 30-day mortality vs. those treated at high-volume centers, whereas those treated by low volume physicians had an increased risk of CABG vs. those treated by high volume physicians.
Richie, JL; Maynard, C; Chapko, MK; et al. Association between percutaneous transluminal coronary angioplasty volumes and outcomes in the health care cost and utilization project 1993-1994. *AmJ Cardiology*. Volume 831, No. 4, February 15, 1999: 493-7.	Nationwide Inpatient Sample from HCUP (20 percent stratified sample of acute care, non-federal hospitals in 17 states)	1993-1994 N = 163,527 (214 hospitals)	Hospital volumes defined as low (< 200 cases per year), medium (201-400), and high (> 400). For both AMI and non-AMI groups, rates of adverse outcomes (defined as same admission surgery and hospital mortality) were lower in high-volume institutions after risk adjustment.
McGrath, PD; Wennberg, DE; Malenka, DJ; Kellett, MA et al. Operator volume and outcomes in 12,988 percutaneous coronary interventions. *JACC*. Volume 31, No. 3, March 1, 1998: 570-576.	Northern New England Cardiovascular Disease Study Group	1990-1993 N=12,988 (5 hospitals; 31 primary operators)	After adjustment for case-mix, higher angiographic and clinical success rates, with fewer referrals to CABG, were seen as operator volume increased. There was a trend toward higher MI rates for high volume operators; all terciles had similar in-hospital mortality rates. There is a significant relation between operator volume and outcomes in PCIs.
Hannon, EL; Racz, M; Ryan, TJ et al. Coronary angioplasty volume – outcome relationships for hospitals and cardiologists. *JAMA*. Vol. 227, No. 11, March 19, 1997: 892-898	Coronary Angioplasty Reporting System of the New York Department of Health	1991-1994 N = 62,670 (31 hospitals)	Patients undergoing angioplasty in hospitals with annual volumes less than 600 experienced a significantly higher risk-adjusted in-hospital mortality rate and risk-adjusted same stay CABG surgery rate.

Study	Data Source	Year(s) of Data/Total Sample Size	Findings
Kimmel, SE; Berlin, JA; Laskey, WK. The relationship between coronary angioplasty procedure volume and major complications. *JAMA*. Volume 274, No. 14, October 11, 1995:1137-1142.	Registries of the Society for Cardiac Angiography and Interventions	1992 – 1993 N = 19,594 (48 centers)	Risk of major complications for labs performing 400-599 procedures per year was significantly lower than that for labs performing fewer than 200 procedures per year and for labs performing 200-399 procedures per year. No significant difference in major complications between the highest volume labs (600+) and labs performing 400-599 procedures per year.
Jollis, JG; Peterson, ED; et al. Relationship between physician and hospital coronary angioplasty volume and outcome in elderly patients. *Circulation*. Vol. 95, No. 11, June 3, 1997: 2485-2491.	Medicare National Claims History File (Part A and B claims)	1992 N = 97,478 (984 hospitals)	After risk adjustment, hospital volume was inversely associated with both in-hospital death and combined end point of in-hospital bypass surgery or death, with improving outcomes seen up to 200 annual Medicare cases. This inflection point is consistent with an overall annual volume of 400 to 600 cases per year.
Jollis, JG; Peterson, ED; Delong, ER et al. The relation between the volume of coronary angioplasty procedures at hospitals treating Medicare beneficiaries and short-term mortality. *NEJM*. Vol. 331, No. 24, December 15, 1994: 1625-1629.	Medicare Provider Analysis and Review (MEDPAR) file from HCFA for hospitalized Medicare enrollees	1987-1990 N = 217,836 (1,194 hospitals)	Higher rates of mortality and CABG observed in all groups of patients treated in hospitals that performed fewer than 100 angioplasty procedures per year on Medicare beneficiaries (this volume can be extrapolated to an overall annual volume of 200 to 400 angioplasty procedures).
Richie, JL; Phillips, KA; Luft, HS. Coronary angioplasty: statewide experience in California. *Circulation*. Vol. 88, No. 6, December 1993: 2735-2743	California Hospital Discharge Data Base	1989 N = 24,883 (110 hospitals)	For both AMI and non-AMI groups, likelihood of having either CABG and/or death was significantly increased at lower volume institutions (< 200) when compared with institutions performing 200 – 400 and greater than 400 cases
Phillips, KA; Luft, HS; Richie, JL. The association of hospital volumes of percutaneous transluminal coronary angioplasty with adverse outcomes, length of stay, and charges in California. *Medical Care*. Vol. 33, No. 5, 1995: 502-514	California Hospital Discharge Data Base	1989 N = 24,856 (110 hospitals)	Rates of adverse outcomes (defined as CABG surgery after PTC and/or in-hospital mortality) were significantly higher than expected in low volume hospitals (<201) and significantly lower than expected in high volume hospitals. (>400).

APPENDIX A.

Summary of Recommended Requirements for Primary PCI Programs: Hospitals with and without On-Site Cardiac Surgery

Table A-1
Summary of Recommended Requirements for Primary PCI Programs: Hospitals with and without On-Site Cardiac Surgery

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Institutional Resources	1) All institutions should provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week.	**Yes**	**Yes**
	2) All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients.	**Yes**	**Yes**
	3) All institutions should have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.	**Yes**	**Yes**
	4) All institutions should have a written commitment by hospital administration signed by the hospital president to support the program, and be required to:	**Yes**	**Yes**
	(i) identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges;	**Yes**	**Yes**
	(ii) develop a formal, regularly scheduled (meetings every other month) interventional case review that requires attendance by a critical mass of interventionalists and other physicians, nurses, and technicians who care for primary PCI patients; and	**Yes**	**Yes**
	(iii) create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes at a minimum the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.	**Yes**	**Yes**
	5) All institutions should design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.	**Yes**	**Yes**

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Institutional Resources (Continued)	6) There must be a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.	**Not Applicable**	**Yes**
	7) There must be a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.	**Not Applicable**	**Yes**
Physician Resources	1) Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year.	**Yes**	**Yes**
	2) Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MI's during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.	**Yes**	**Yes**
	3) Physicians who perform primary PCI should agree to participate in an on-call schedule.	**Yes**	**Yes**
	4) Physicians who perform primary PCI should meet the credentialing criteria for the institution.	**Yes**	**Yes**
Initiation of New Primary PCI Program	1) The Maryland Health Care Commission should establish an application process to review requests submitted by hospitals seeking approval to provide primary PCI services without on-site cardiac surgery services.	**Not Applicable**	**Yes**
	2) All institutions should demonstrate that they have a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MI's annually.	**Yes**	**Yes**

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Initiation of New Primary Angioplasty Center Program (Continued)	3) Because primary PCI is a strategy of care involving a team of health care professionals in multiple care areas, all institutions should begin providing this service only after completing a development program that attends to setting of standards, training of staff, development of logistics and implementation of a formal quality and error management program. The application submitted to the Commission should describe in detail how the hospital proposes to undertake and complete a development program, which may include collaboration with an established primary PCI program. The development program should contain the following major components:		
	(i) The standards contained in the American College of Cardiology/American Heart Association Guidelines for Management of Patients with Acute Myocardial Infarction and Guidelines for Percutaneous Coronary Intervention will be used to guide care provided in primary PCI programs.	**Yes**	**Yes**
	(ii) Nursing and technical staff in both the catheterization laboratory and in pre and post-procedure care units will require additional training, including familiarization with angioplasty equipment, commonly used drugs, intra-aortic balloon counterpulsation equipment, patient transfer to and from the laboratory, and other pre-and post-procedure care issues.	**Yes**	**Yes**
	(iii) The logistical issues that need to be addressed in the primary PCI development program include at a minimum: hours of operation, who obtains consent, mechanisms to gather staff, mechanisms to assure availability of staff and catheterization laboratory, plans for recurrent ischemia or infarction, plans to determine the responsible physician during and after primary angioplasty, plans for failed angioplasty, and fall-back plans for primary angioplasty system failure.	**Yes**	**Yes**
	(iv) The quality and error management component of the primary angioplasty development program should give special emphasis to minimizing, discovering, reporting, and correcting error in the system of acute MI care.	**Yes**	**Yes**
Patient Groups Suitable for Primary Angioplasty in Settings without On-Site Cardiac Surgery	a) ST-segment elevation myocardial infarction (or new LBBB or ST-depression V1-V2 compatible with true posterior infarction) who are thrombolytic eligible or thrombolytic ineligible.	**Yes**	**Yes**
	b) When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, either because the patient is too unstable or because the temporal delay will result in worse outcomes.	**Not Applicable**	**Yes**
	c) Patients for whom the primary PCI system was not initially available, who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of all cases.	**Yes**	**Yes**

Minimum and Optimal Institutional Volume	All institutions should perform a minimum of 36 and optimally 49 primary PCI procedures annually. *(Note: A program performing at least 49 cases annually, or approximately one case per week, is more likely to have the logistics and staff available for timely reperfusion of acutely ill patients. If, however, rapid access to a program doing 49 cases is not available, then a site performing 36 or more cases/year is acceptable. This approach acknowledges important regional differences in access to primary PCI services. The lower volume standard should only be considered in areas of the state where access to a high volume program is not readily available.)*	**Yes**	**Yes**
Process and Outcome Measures for On-Going Quality Assessment	Monitoring of the outcomes of care for patients presenting with ST-elevation MI will facilitate on-going quality improvement efforts and provide the opportunity to measure program compliance, safety, and effectiveness. This requires that a uniform data set be developed, collected, and analyzed from all hospitals in Maryland offering primary PCI services. This data set should build upon the elements collected in the C-PORT project. Included would be data on: patient demographic and clinical characteristics; times of symptom onset, arrival in the emergency department, arrival in the catheterization lab, catheterization procedure onset and termination, balloon inflation, procedural outcome; complications; need for emergency cardiac surgery; incidence and indication for hospital transfers, adjunctive medical therapies and clinical outcomes (including in-hospital mortality and stroke and long-term follow-up).	**Yes**	**Yes**

Appendix B.

Meeting Minutes: Interventional Cardiology Subcommittee

September 4, 2002
October 16, 2002
January 27, 2003
March 10, 2003
April 14, 2003

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care
Interventional Cardiology Subcommittee

September 4, 2002
BWI Airport Marriott Hotel
1743 West Nursery Road, Baltimore, Maryland 21240

Committee Members Present

David O. Williams, M.D., Chairman
Robert R. Bass, M.D.
George Bittar, M.D.
Sridhur Chatrathi, M.D.
Charles Cummings, M.D.
Michael Fiocco, M.D.
Candice Fonke, R.N.
Scott Friedman, M.D.
Frank Gravino, M.D.
Bartley Griffith, M.D.
William Herzog, M.D.
Roy Leiboff, M.D.
Keith M. Lindgren, M.D.
Steve B. Lowenthal, M.D.
Catherine L. Monge
Robin P. Newhouse, R.N.
Hilary T. O'Herlihy, M.D.
Stephen H. Pollock, M.D.
Bernard Rubin, M.D.
Mitchell Schwartz, M.D.
Dominic Seraphin
Karen Stair

Committee Members Absent

James L. Field, Ph.D.
Mark Midei, M.D.
James Porterfield, M.D.
Sidney Smith, M.D.

Members of the Public Present

Lucy Ferko, St. Joseph Medical Center
Sean P. Flanagan, Director, Government Relations, St. Joseph Medical Center
Gary Jones, Shore Hospital System of MD
Martha Nathanson, Lifebridge Health
Jack Neil, Anne Arundel Medical Center

Commission Staff Present

Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Colleen Lates

1. Call to Order and Introductions

David O. Williams, M.D., Chairman of the Interventional Cardiology Subcommittee, called the meeting to order at 3:00 p.m. Members of the Interventional Cardiology Subcommittee and Maryland Health Care Commission staff introduced themselves.

2. Overview and Background

In his introductory remarks, Dr. Williams said that he was the Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital. He said that the issues to be considered by the Interventional Cardiology Subcommittee were important for patients, hospitals, and physicians throughout Maryland. Dr. Williams noted that it was likely that the Subcommittee would be getting inquiries from other states regarding its discussions. He also stated that answering questions posed in the subcommittee charge would be a difficult task and that debate among Subcommittee members was expected. Dr. Williams concluded this remarks by outlining how the subcommittee would function in taking positions on issues.

Dr. Williams asked Ms. Pamela Barclay, Deputy Director for Health Resources, to provide an overview of the Commission. Ms. Barclay thanked the Subcommittee members for taking time from their busy professional and personal lives to participate in advising the Commission on issues relating to interventional cardiology services. Then Ms. Barclay provided a brief overview and description of the activities and programs of the Commission. The presentation provided the history of the Steering Committee and its four Subcommittees (Quality Measurement and Data Reporting, Interventional Cardiology, Long Term Issues, and Inter-Hospital Transport). According to Ms. Barclay, the charge to the Interventional Cardiology Subcommittee includes the following issues:

1. Should State health planning policy be modified to permit hospitals to perform primary angioplasty without the requirement for on-site cardiac surgery?

- How do outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery compare with outcomes in hospitals with on-site surgery?
- What institutional resources are required for a primary angioplasty program?
- What are the program development requirements for a primary angioplasty program?
- Is there a relationship between volume of primary angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?
- What process and outcome measures should be used for on-going quality assessment?

- Which patient groups are suitable for primary angioplasty in settings without on-site cardiac surgery?

2. Should State health planning policy be modified to permit hospitals to perform elective angioplasty without the requirement for on-site cardiac surgery?

- Is there evidence that current policy restricts availability of elective angioplasty services to Maryland patients?
- How do outcomes of elective angioplasty performed in hospitals without on-site cardiac surgery compare with the outcomes of elective angioplasty performed in hospitals with cardiac surgery?
- Should the Commission consider a pilot project study to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients?
- How should this pilot project be designed and implemented? What would be the resource and program development requirements for a participating hospital?
- What process and outcome measures should be used for on-going quality assessment?
- Is there a relationship between volume of elective angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?
- Which patient groups would be suitable for inclusion in a pilot program study of elective angioplasty?

3. Discussion of the Subcommittee Charge, Structure, and Timetable

Dr. Williams asked if any of the Subcommittee members had questions. Keith Lindgren, M.D. asked who maintains C-PORT registry data. Ms. Barclay replied that Tom Aversano, M.D. at Johns Hopkins Hospital maintained the C-PORT registry. Dr. Williams said that Dr. Aversano, could be invited to advise the Subcommittee about the C-PORT project.

Hilary T. O'Herlihy. M.D. raised the issue of having members from other states involved in deliberating Maryland's policies governing interventional cardiology services. Ms. Barclay responded that she understood Dr. O'Herlihy's position, but noted that the inclusion of other state representatives was a way of adding expertise to the discussions. Stephen H. Pollock, M.D. commented that including representatives from other states was a good idea and a way to minimize institutional bias in discussing issues.

Charles Cummings, M.D. asked how many hospitals in Maryland perform angioplasty. He suggested that the Subcommittee consider collecting data from existing programs on the characteristics and outcomes of angioplasty procedures. Dr. Williams recommended that a document be developed to summarize scientific information that is available concerning angioplasty procedures. He said that he had talked with Chris

Cannon, M.D. in Massachusetts about developing that type of "state of the evidence" white paper for the subcommittee. Dr. Williams noted that a similar document was helpful to Rhode Island. He added that American College of Cardiology guidelines should also be made available to be subcommittee. Dominic Seraphin stated that there was also a need for information on a range of issues, including transportation, geographic location (metropolitan versus rural area), cost, and personnel.

Dr. Williams agreed and said there are subgroups of patients as well as subgroups of environments that should be considered by the subcommittee. Regarding C-PORT, he noted that Dr. Aversano could possibly share the lessons learned from the C-PORT project regarding operational issues with the subcommittee. Dr. Pollock recommended that inter-hospital transport issues be considered and noted several Baltimore area hospitals were beginning to track information regarding arrival at the hospital, arrival at the cath lab, and outcomes for primary angioplasty patients. He said that this data should be available to be subcommittee by December 2002. Dr. Pollock said he was also a member of the Inter-Hospital Transport Subcommittee and the information he gathers would be shared with that subcommittee as well as the Interventional Cardiology Subcommittee.

Dr. Williams commented that it might be a good idea to include inter-hospital transport as well as emergency medical services (EMS) protocol considerations in the subcommittee discussion. Scott Friedman, M.D. said that travel distances were important to consider in weighing options for planning primary angioplasty services. Mitchell Schwartz, M.D. agreed and said the cost impact of driving had to be considered. Dr. Cummings mentioned that overlap is important since helicopters are not always available to transport patients between hospitals.

Bernard Rubin, M.D. asked about the quality of care implications if a patient were taken to a hospital that does not offer angioplasty? Dr. Williams replied that the service could be considered like trauma. Robert R. Bass, M.D. said that the trauma system is voluntary, but there are certain protocols. The overwhelming majority of trauma patients in Maryland receive care in a trauma center. According to Dr. Bass, regulations regarding trauma centers are already in place and it would not be difficult to add another type of service to the regulations.

Dr. Schwartz asked about the cost. He said the cost would different in Baltimore when compared to Hagerstown. Dr. Bass stated that with respect to trauma, volume makes a significant difference in outcome. Dr. Williams then asked the subcommittee if there were additional questions that should be added other than regionality and EMS. Dr. Cummings said that overall costs needed to be considered. He asked how much the costs would be and how much equipment would be needed if the Subcommittee said that C-PORT is a standard of care and should be offered by every hospital. Dr. Schwartz stated there might not be enough staff. He asked if anyone was dealing with the topic of staff and Ms. Barclay replied that staffing was not a specific topic that was assigned to any one subcommittee.

Dr. Friedman commented that a patient receives thrombolytics because primary angioplasty may be unavailable many times. Dr. Williams said this relates to the volume issues and he suggested that staff organize available information on myocardial infarction prevalence in Maryland. Dr. Williams noted there is a plan underway in Boston to have EMS only go to the hospital with angioplasty. This plan will be monitored. Eighty to ninety percent of the time the service has to be provided. Dr. Williams said the process and outcome measures noted in the subcommittee charge would tie into the work of the Quality Measurement and Data Reporting Subcommittee.

Frank Gravino, M.D. stated if hospitals do not have a team available at night it would be difficult to consider the service dedicated to 24/7 availability. In metropolitan areas, it is easy to get experienced cardiologists, but in regions with no open heart programs, it is often difficult to get qualified staff. Dr. Williams stated that physician requirements should be considered and that support staff is also an important operational issue. Roy Leiboff, M.D. urged the subcommittee to look at cost issues. The cost analysis has to be compared to saving one life vs. the cost of other interventions. Dr. Pollock said that the focus should be on what is best for patient care.

George Bittar, M.D. asked if a hospital participated in C-PORT and met time frames whether there would be a way to track the service use 24-hours a day. Dr. Pollock commented there was a difference in having C-PORT and using it. Dr. Cummings said that thrombolytics could also be tracked. He also commented on the concept of an on-call team to go where there are more AMI's than physicians on call.

Dr. Pollock stated the subcommittee had a responsibility to assure that people in Maryland get the same coverage regardless of where they live. The State should treat cardiac patients like trauma patients. Dr. Cummings said there is a problem rotating an experienced interventionist for 50 MI's a year. There are not enough to hire and wait for MI's to occur. Dr. Pollock said his facility has two interventionists on duty every weekend. Bartley Griffith, M.D. stressed the importance of considering regionality in the deliberations.

Dr. Bass said there had been early anxiety about community hospitals and hospitals without trauma centers. Early consideration of primary angioplasty will result in a similar stigma. Dr. Pollock commented that patients want to get to the hospital as quickly as possible and they should have access to care. Dr. Rubin mentioned there is a link between primary angioplasty and elective angioplasty and the Subcommittee should discuss defects in various areas. When angioplasty is performed in a center, additional backup might be required. Dr. Griffith asked, "Are we to think there won't be an increase in surgery centers?" Ms. Barclay said projections are identified in the State Health Plan through 2002, which will be updated during 2003. She noted that available trend data does not show substantial increases in the volume of open heart surgery cases.

Dr. Lindgren stated that the Subcommittee had to look at outcomes. Are the results of C-PORT without cardiac surgery backup comparable to hospitals with cardiac surgery backup? Dr. Friedman pointed out that in Baltimore City there were multiple

programs within close proximity. On the other hand, in more rural areas it can take considerable time to find a hospital willing to take a patient and then transfer that patient.

Dr. Williams said there are a lot of questions about C-PORT. He said he hoped the Subcommittee has a presentation from Tom Aversano, M.D. at the next meeting.

4. Future Meeting Schedule

Dr. Williams stated that the Interventional Cardiology Subcommittee would meet again around in early October and that staff would poll members to find the best date.

5. Other Business

There was no other business.

6. Adjournment

The meeting adjourned at 4:50 p.m.

Summary of the Meeting of the Advisory Committee on
Outcome Assessment in Cardiovascular Care
Interventional Cardiology Subcommittee

Wednesday, October 16, 2002
Hyatt Regency Baltimore
Baltimore, Maryland 21202

Subcommittee Members Present

David O. Williams, M.D., Chairman
Robert R. Bass, M.D.
George Bittar, M.D.
Sridhur Chatrathi, M.D.
Charles Cummings, M.D.
James L. Field
Michael Fiocco, M.D.
Scott Friedman, M.D.
Bartley Griffith, M.D.
Frank Gravino, M.D.
William Herzog, M.D.
Roy Leiboff, M.D.
Keith M. Lindgren, M.D.
Steve B. Lowenthal, M.D.
Mark Midei, M.D.
Catherine L. Monge
Robin P. Newhouse, R.N.
Hilary T. O'Herlihy, M.D.
Stephen H. Pollock, M.D.
Bernard Rubin, M.D.
Mitchell Schwartz, M.D.
Dominic Seraphin

Subcommittee Members Absent

Candice Fonke, R.N.
Frank Gravino, M.D.
James Porterfield, M.D.
Susheel Sharma, M.D.
Sidney C. Smith, M.D.
Karen Stair

Members of the Public Present

Thomas Aversano, M.D., Johns Hopkins
Lynnet Aversano, Coordinator, C-PORT
Andrew Cohen
Sean P. Flanagan, Director, Government Relations, St. Joseph Medical Center
Gary Jones, Shore Health System
Martha Nathanson, LifeBridge Health
Jack Neil, Anne Arundel Medical Center
Stan Watkins, M.D., Johns Hopkins

Members of Other Subcommittees

Henry Meilman, M.D.

Commission Staff Present

Barbara G. McLean
Pamela W. Barclay
Colleen Lates
Bridget Glazebrook
Susan Panek
Debbie Rajca
Dolores Sands

1. Welcome and Introductions

David O. Williams, M.D., Chairman of the Subcommittee, called the meeting to order at 3:07 p.m., and asked the Subcommittee members to re-introduce themselves.

2. Approval of the Previous Minutes (September 4, 2002)

Dr. Williams called for consideration and approval of the minutes of the Subcommittee's first meeting, held on September 4, 2002. Dr. Lowenthal moved their approval; Dr. Friedman seconded his motion. The minutes of the September 4, 2002 meeting were adopted as presented.

3. Presentation and Discussion on the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Project (Thomas Aversano, M.D.)

Dr. Williams set the stage for Dr. Aversano's presentation on the results and the lessons of the C-PORT project by sharing some of his own thoughts, prompted by the Subcommittee's initial meeting and discussion, in order to create a framework in which to understand and apply the C-PORT experience. The Subcommittee's charge poses several important questions, one of which addresses the appropriateness and safety of permitting primary angioplasty to be performed without a cardiac surgery program back-up. Because the C-PORT study and registry is an ongoing investigation of that question, Dr. Williams asked Dr. Aversano to focus on three aspects of his work: the data from the formal clinical trial, the additional information obtained since the trial became a data registry, and the lessons from both phases of C-PORT that could inform the work of this Subcommittee.

Dr. Williams presented several slides of "broad observations" to shape the group's discussion of C-PORT and its applicability to the Subcommittee's recommendations. His decision diagrams traced the choices available, in responding to a case of acute myocardial infarction (AMI) in the field, by EMS personnel (transport to the closest ED available, or to an ED at a hospital with primary cardiology interventional capability?) as well as to an AMI presenting to an emergency department (thrombolytic therapy – if indicated -- followed by PCI on site, in the C-PORT model, or off-site?) Woven through these choices, of course, are issues of inter-hospital transport, of lessons learned from recent studies about how to facilitate transport decisions, of geography and available resources. Dr. Williams noted that, within the time frame available to the Subcommittee and to the Advisory Committee (although it has been extended by some months) an "all-inclusive" solution may not be possible. What the Subcommittee recommends, he observed, is likely to be an initial step, with further evaluation and monitoring through ongoing data collection and analysis certain to suggest further changes as time goes on, and the state of the art continues to advance.

In response to Dr. Williams' comments, Dr. Aversano observed that the information he was about to present represents one of the range of options in this area, about which "all of the data is not yet there." Dr. Williams concluded his introductory remarks by observing that the Subcommittee's main concern – its "fiduciary responsibility" – is to determine what is "best for the people of Maryland," and make its recommendations to the Advisory Committee accordingly.

- **Review of C-PORT Study Methods and Results**

Dr. Aversano began his review of the first phase of C-PORT, in which it was a formal clinical trial, by noting some of the other significant trials and studies that had raised the issue of the safety and efficacy of primary angioplasty, with or without thrombolytic therapy. He characterized the purpose of the C-PORT clinical trial as investigating the theory, which developed in the course of these studies, that the availability of primary angioplasty to patients presenting at emergency departments with AMI represented a "huge benefit." C-PORT would undertake to evaluate that evolving belief, to see if those benefits accrued to the "real world" situations presenting to community hospitals, and not just to tertiary centers with larger volumes. The clinical trial posed the question of whether access to primary angioplasty for AMI patients could, and should, be expanded.

Dr. Aversano explained the criteria for inclusion of cases, which received care prescribed by the C-PORT clinical protocols, once informed consent was obtained. Outcomes of trial patients as compared to the control group at six weeks, and at six months, showed a similar reduction of adverse events among the trial group -- a 40% reduction at six weeks, and a 38% reduction at six months. C-PORT found statistically significant benefits to the use of primary angioplasty in AMI cases, even though the subgroup studied was a smaller segment of a relatively small sample of cases. Other findings included a significantly higher rate of bleeding in the primary angioplasty group, and a lower rate of subsequent angioplasties (19.5% of those receiving medical intervention, as compared to 13% of patients who received primary angioplasty.) Length of stay and subsequent transfers were also lower in the angioplasty group.

Dr. Aversano characterized the conclusion reached in C-PORT's clinical trial phase as finding significant benefit from the availability of primary angioplasty to patients presenting with AMI "in a formal primary PCI development program, whose outcomes are monitored." He emphasized the importance of understanding that this phase of C-PORT did <u>not</u> show: that all hospitals with cardiac catheterization laboratories should do primary angioplasties.

- **New Data in the C-PORT Registry**

At the end of the randomized trial, the C-PORT team concluded that it needed more information, derived from more procedures than the 225 examined in the course of the trial; consequently, C-PORT was shifted to a registry of procedures and data. To date, the cumulative C-PORT total now stands at 881 patients, 87% of whom were

thrombolytic-eligible. Primary angioplasty was attempted on 85% of the total, or 767 patients, and was successful in 97% of cases. Median time from door to cath lab stands at 69 minutes, with a median door-to-balloon time of 108 minutes. Patients in the combined C-PORT trial and registry who have been thrombolytic-eligible have experienced an overall mortality of 3.5%, with a 3.2% mortality among thrombolytic-eligible cases that did not receive primary angioplasty. Mortality among C-PORT registry patients who were not candidates for thrombolytic therapy is 12.3%. The annual average stands at 51 cases per year. A meta-analysis, which examines C-PORT's data and findings as part of all of the cases involved in the other major studies of these issues (which stood at 2,500 patients at the time C-PORT converted to a registry, and is now at 7,739 cases and growing) shows that lower volume programs experience higher mortalities. Dr. Aversano ended the data-focused portion of his presentation with the observation that, as the number of cases continues to grow, analysis of the data becomes stronger.

- **Observations and Lessons Learned**

Dr. Aversano then presented some perspectives on the C-PORT experience, beginning with a discussion of the "progress in AMI care, from the high-mortality, "pre-CCU" days to the 2002 "Post-Thrombolytic Era." He questioned whether, in fact, we are definitively in a truly "post-lytic era," since no single study demonstrates this conclusively. Dr. Aversano urged the Subcommittee to focus on the creation of "systems of care," in which primary angioplasty assumes a proportional importance. Rather than simply seeking to expand the capacity for primary angioplasty in the system as a whole, we should focus on establishing a framework in which the "common goal" of "maximum access to safe, appropriate, and prompt primary cardiac intervention" is assured. A rational system of inter-hospital transport must be a part of that framework, as well as quality and error management, with universal monitoring and a standardized data collection system.

The importance of understanding what factors do and do not promote this access to primary cardiac intervention, Dr. Aversano pointed to the Danish study in which, if an AMI case arrived at a non-PCI hospital, the patient was given thrombolytic drugs on a randomized basis, and transferred to a PTCA hospital. PCI was found clearly superior, and the study was ended – but the administrative and clinical activities in the transporting hospital caused much of the additional time-to-treatment, not the transport itself. This suggests that the major delay in obtaining appropriate treatment continue to be in-hospital processes, most related to identification of the patient, locating any available medical and insurance information.

Any system Maryland adopts also has to recognize that transporting patients to hospitals at which PCI is available "is not 100% safe," and, consequently, determining what staff need to be transported with the patient, as well as minimizing the time in which transport – regardless of weather conditions – is unavailable. The model to which many would turn in this regard is the trauma system, but this is an expensive choice, and not how the majority of AMI cases enter the system.

Dr. Aversano presented the "ideal" system, at the present time, as one that permits PCI without cardiac bypass surgery backup, under "very specific criteria," with universal monitoring of outcomes using standard data definitions. Under this ideal design, risk-adjusted outcomes data would be used to "inform health care policy over time," so we can keep refining this system over time.

Dr. Aversano maintained that the State should establish criteria for participation in this system, requiring adequate volumes of PCI cases, in the range of 36-49 cases per year; 24-hour, seven-days-a-week operation; standards for the certification and especially the number of practitioners at a given center, with a minimum of three to four; commitment to program development and maintenance, with ACC/AHA standards for logistics and quality improvement, outcomes reporting to keep standards high, and internal quality evaluation and improvement processes. The criteria should require an affiliation with a tertiary hospital, a practiced transport plan, and ongoing training and peer review. Data on outcomes and quality improvement measures should be reported to the Commission.

Guidelines for the closure of these PCI centers are as important as the criteria under which they would be established. The centers should be required to close under standards related to poor outcomes, low volumes, and poor practitioner availability and support. Dr. Aversano said that he is convinced of the absolute need for universal standardized data reporting, and the need to establish a committee to review outcomes, and prepare an annual report on the continuing development of the system of care.

In response to questions from Dr. Rubin, Dr. Aversano said that two of the existing C-PORT hospitals do not operate on a 24-7 basis, and that an attempt was made, in the Danish study, to establish a triage model for use in hospitals without PCI capability, through which to identify cases that would benefit from quick transport to PCI hospitals. The triage process can be complicated, however, by the varying competence of ED physicians, by the demand on their time at peak periods, and by the difficulty of diagnosing AMI. Dr. Rubin emphasized the need for a good in-hospital triage system; Dr. Williams added that the use of EKG in the field can be extremely beneficial in expediting care decisions for an incoming patient. Dr. Bass noted that the emergency transport system has continued to struggle with the issue of – and with determining appropriate protocols for – pre-hospital triage in cardiac cases. Transporting patients to the most appropriate hospital will help make transport available more quickly for the next case, he observed. Dr. Aversano agreed, and noted that none of these measures – field EKGs, pre-hospital triage protocols – are mutually exclusive. Establishing a set of criteria through which hospitals may continue to develop or refine PCI programs will present an opportunity to "examine a heterogeneous system" through analysis of universally collected, standardized outcomes data, and these real numbers will give us a chance to shape the system to work better, based on experience.

Dr. Cummings observed that the goal for C-PORT is 24-7 operation, and expressed concern that "if all hospitals participate in C-PORT," this would represent a

bad use of already-scarce staff resources for the system as a whole, and result in "sub-optimal care to a lot of patients." He asked Dr. Aversano if having a PCI program in every hospital would cause quality of care to suffer, by stretching available interventional cardiologists and other staff over too many programs. Dr. Aversano responded that if a hospital cannot cover the service, it should not seek to establish a PCI program, and that this concern highlights the importance of establishing clear criteria for these PCI programs, to which all centers commit as a condition of continuing operation. Dr. Bass underscored the importance of a system framework: if several trauma cases hit community hospitals at once, MIEMSS knows their capabilities, and can divert patients as need, through its system.

Mr. Field noted that the Cardiovascular Roundtable compared the two therapies four years ago, in its examination of the use of primary angioplasty in New Hampshire. Over time, and over all studies, he observed, his organization has learned that primary angioplasty can be appropriately done without on-site surgery – but that there are specific, unique requirements that need to be in place. He raised the question of why hospitals want to do primary angioplasty without a CABG program in place, since the programs are high cost, resource-intensive, typically low volume, and there is "not a monetary return at stake." He said that, for hospitals that choose to establish these programs, the state should put into place these specific criteria, along the lines of those Dr. Aversano described earlier; the criteria themselves should weed out many institutions, which will not be able to comply. The "real issue," he observed is what the future of these interventional cardiology programs will be – will those hospitals performing PCI on an emergency basis wind up doing elective cases, where the larger volumes and real money lie? The Commission will have to look at this issue, because emergency interventions represent only one part of the larger picture.

Dr. Williams agreed that the Subcommittee, and ultimately the Commission and the State, will have to address both emergency and elective PCI procedures. Dr. Pollock urged that the focus remain on what is good for patients with acute MI, and that the system framework described by Dr. Aversano provides the most appropriate model under which to proceed. Dr. Cummings reminded the Subcommittee of Dr. Williams' opening remarks, and of the potential distinction between "what's best for patients" versus the Subcommittee's "fiduciary responsibilities." He asked about the possibility of a study that would encompass all available data, including about AMIs not within the C-PORT program, and to introduce elements of the DANAMI study, bringing "high-end transport" to high AMI hospitals, as a comparison. Dr. Aversano responded that, in essence, that would be what a varied but integrated system such as the one he proposes would offer – the opportunity, and the responsibility, to collect standardized outcome data from a range of choices in AMI treatment, and to use the results to continually evaluate and improve the system of care.

There was general agreement that the issue of elective angioplasty without cardiac surgery backup is "not going away," that it is a national issue. Mr. Field observed that most involved in the issue recognize the "psychological hurdle," the persistent belief that surgery on site is still needed. Dr. Aversano noted that an article in that day's *Journal of*

the American Medical Association reported a study linking volume and quality – fewer cases, higher mortality – and connecting that finding to states with CON requirements for cardiac surgery and elective angioplasty, which seek to maintain high volumes by limiting the number of programs.

4. Future Meeting Schedule

Pamela Barclay, Commission Deputy Director for Health Resources, told Subcommittee members that they would be polled about dates for future meetings. She noted that the next meeting of the Advisory Committee would be a joint meeting with the Subcommittee on Quality Measurement and Data Reporting, and would feature a presentation on the Northern New England data collection and outcome improvement effort by Dr. William Nugent.

5. Other Business

There was no other business.

6. Adjournment

The meeting adjourned at 5:00 p.m.

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care Interventional Cardiology Subcommittee

Monday, January 27, 2003
4160 Patterson Avenue
Baltimore, Maryland 21215

Subcommittee Members Present

David O. Williams, M.D., Chairman
Charles Cummings, M.D.
Candice Fonke, R.N.
Scott Friedman, M.D.
Frank Gravino, M.D.
William Herzog, M.D.
Steve B. Lowenthal, M.D.
Catherine L. Monge
Stephen H. Pollock, M.D.
James Porterfield, M.D.
Bernard Rubin, M.D.
Dominic Seraphin
Karen Stair

Subcommittee Members Absent

Robert R. Bass, M.D.
George Bittar, M.D.
Sridhur Chatrathi, M.D.
James L. Field
Michael Fiocco, M.D.
Bartley Griffith, M.D.
Roy Leiboff, M.D.
Keith M. Lindgren, M.D.
Mark Midei, M.D.
Robin P. Newhouse, R.N.
Mitchell Schwartz, M.D.
Susheel Sharma, M.D.
Sidney C. Smith, M.D.

Members of the Public Present

Vanessa Aburn, Union Memorial Hospital
Andrew Cohen
Sean P. Flanagan, Director, Government Relations, St. Joseph Medical Center
Wynee Hawk, GBMC Healthcare
Jeff Johnson, Shore Health System
Gary Jones, Shore Health System
Martha Nathanson, LifeBridge Health
Vanessa Purnell, MedStar Health
Lucy Shamash, SJMC

Members of Other Subcommittees

Henry Meilman, M.D.

Commission Staff Present

Barbara G. McLean
Pamela W. Barclay
Colleen Lates
Bridget Glazebrook
Susan Panek
Debbie Rajca
Dolores Sands

2. Welcome and Introductions

David O. Williams, M.D., Chairman of the Subcommittee, called the meeting to order at 3:07 p.m., and described the materials forwarded to subcommittee members for the review. To provide background material for this discussion, Williams noted that Tom Aversano, M.D. had presented data on the C-PORT study methods and results at the previous subcommittee meeting. A copy of the slides from that earlier presentation was enclosed in the meeting materials. In addition, a letter from Aversano that outlines his suggestions for how current policies governing primary angioplasty should be modified was provided to subcommittee members. Williams said that he had requested that Tom Wharton, M.D. give the subcommittee his thoughts on the questions posed in the subcommittee's charge. Wharton's response was included in the meeting materials. Although the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines are now under revision, the mailout package includes a copy of the current *Guidelines for Percutaneous Coronary Intervention (A Revision of the 1993 PTCA Guidelines)* for reference. In addition, Chris Cannon, M.D. examined the subcommittee questions from the standpoint of developing a triage system for acute myocardial infarction similar to the trauma model, where patients with ST elevation myocardial infarction (STEMI) are transported immediately to a hospital with primary PCI capability. The mailout package includes his response and the Boston Acute MI Plan. Finally, Williams noted that the mailout package includes two recent journal articles regarding primary angioplasty.

According to Williams, the goal for the meeting is to discuss and answer each question posed in the charge to the subcommittee regarding primary PCI. He encouraged subcommittee members to express their views and said that the report forwarded to the Steering Committee would reflect areas of agreement as well as disagreement. In spite of all of the work that has been done on primary PCI, Williams noted that there are data voids or unanswered questions based on the results of clinical trials or evidence-based medicine to date. The purpose of the discussion today is to recommend a policy that is in the best interests of the residents of Maryland which may be different that the interests of individual hospitals, health systems, and physician practices, or other individual concerns. He remarked that the discussion should focus on developing the best possible policy recommendations and should not be a joust or debate based on who can craft the best argument.

Williams briefly reviewed the *ACC/AHA Guidelines for Percutaneous Coronary Intervention (A Revision of the 1993 PTCA Guidelines).* He noted the classifications employed by ACC/AHA should serve as a resource to the subcommittee. These classes summarize the indications for PCI as follows:

Class I: Conditions for which there is evidence for and/or general agreement that the procedures or treatment is useful and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

Class IIA: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIB: Usefulness/efficacy is less well establish by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective, and in some cases may be harmful.

Williams also reviewed the ACC/AHA recommendations for PCI institutional and operator volumes at centers with on-site cardiac surgery (Table 14, pages 19-20 of the Guidelines for PCI). On page 22 of the ACC/AHA guidelines, he reviewed the recommendations for performing PCI with and without on-site cardiac surgery presented in Table 17. Williams explained that the ACC/AHA guidelines established primary PCI in facilities without on-site cardiac surgery as a Class IIB indication. He said two committees (ST-Segment Elevation MI Committee and the PCI Committee) were currently in the process of reviewing this classification. While the final recommendation has not been made, Williams said that the classification would likely be IIA or IIB but would not likely move to a Class I. He also noted the recommendations for primary PCI acute transmural MI patients as an alternative to thrombolysis contained in Table 25 (page 31) of the ACC/AHA guidelines.

Williams noted that the materials provided for the subcommittee deliberations reflected the opinions of different people. The goal is to be fair and unbiased in conducting the subcommittee's assessment to develop final recommendations.

2. Approval of the Previous Minutes (October 16, 2002)

Williams called for consideration and approval of the minutes of the Subcommittee's first meeting, held on October 16, 2002. Dr. Charles Cummings moved their approval, with a second by Dr. Stephen Pollock. Dr. Frank Gravino noted that he had arrived late to the meeting, but was in attendance. The minutes of the October 16, 2002 meeting were adopted as corrected.

3. Review of Data and Discussion of Questions Posed in the Subcommittee Charge Regarding Primary Percutaneous Coronary Interventions (PCI)

Williams asked the subcommittee whether they agreed with the statement that when possible a strategy of coronary intervention is preferable to a strategy of thrombolytic therapy. It was the consensus of subcommittee members that under ideal circumstances coronary intervention is the preferable strategy. With respect to the role of electrocardiograms in the field (i.e., the ability to identify the patient with acute ST-segment elevation MI before the patient arrives at the emergency department), Williams asked whether the subcommittee agreed that this is a key component of any plan regardless of strategy. He recommended, and the subcommittee agreed, that one the recommendations to the Steering Committee address the need to expand the use of electrocardiograms in the field.

- **How do outcomes of primary PCI performed in hospitals without on-site cardiac surgery compare with outcomes in hospitals with on-site cardiac surgery?**

Williams reviewed the response prepared by Wharton to the question regarding how outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery compare with outcomes in hospitals with an on-site cardiac surgery program. According to Wharton, reports from programs without on-site cardiac surgery indicate that primary angioplasty can be provided safely and effectively in a high-risk population, with outcomes similar to those reported from high volume cardiac surgical centers. Williams asked Subcommittee members for comments on Wharton's analysis.

Dominic Seraphin said that he was not able to identify a study in the medical research that answered the question posed in the subcommittee's charge. He indicated that available studies addressed high volume versus low volume angioplasty programs but not outcomes of programs with on-site cardiac surgery versus without on-site cardiac surgery backup. Dr. Scott Friedman noted that the data from the Sanborn article referenced in the Wharton paper was a large study that compared outcomes of primary angioplasty at surgical hospitals to those at hospitals without on-site cardiac surgery. This study concluded that there was no significant difference in mortality between the two types of hospitals. Williams pointed out that a limitation of the Sanborn study was the use of registry data. He noted that a shortcoming of any registry database was the to ability compare patient groups.

Pollack questioned whether the outcome data analyzed included patients with cardiogenic shock. He noted the importance of adjusting outcome data for important differences in case-mix. Cummings said that a prospective randomized study was needed to address the outcome issue. While there was data clearly supporting the conclusion that primary angioplasty was preferable to thrombolysis, it was not clear whether transferring versus treating patients in community hospitals without cardiac surgery was preferable. Pollack said that C-PORT proved that hospitals without cardiac surgery could perform primary angioplasty and have reasonable outcomes. Pollack said that there was no direct comparison that answered the question of whether a patient would do better staying at a community hospital or whether outcomes would be improved by transferring the patient. Cummings noted that travel times were an important consideration because a patient at some distance from a tertiary center might experience better outcomes.

Williams stated that there is a data void in this area. The registry data are helpful and indicate that in selected cases you can achieve a certain result without on-site cardiac surgery. Whether the result is inferior, superior, or the same as what would happen if the same patient went to an established program is unknown. Williams said, and the subcommittee agreed, that the registry data show that hospitals without on-site cardiac surgery can do primary angioplasty and achieve results superior to thrombolysis at the same site but whether the results are the same, better, or worse than hospitals with established programs and on-site cardiac surgery is unknown. There is not a direct,

randomized trial that addresses this comparison. Williams pointed out that Aversano's earlier presentation before the subcommittee agreed with this statement.

Seraphin noted that is was important for the subcommittee to consider the question of public need for primary PCI (i.e., how many patients in Maryland are likely to require this service on an average day). Williams agreed and said that the subcommittee should end up talking about need. He noted that after the subcommittee defines the ideal service it would be important to consider access to that service as defined by the subcommittee. Access for primary angioplasty services should reflect time. On a statewide basis, Williams noted that it was important to consider the ability of patients to obtain the resource defined by the subcommittee. In Baltimore, need would be different than in, for example, Western Maryland or the Eastern Shore. Williams indicated that the question of need was not just how many patients but whether existing resources met what the subcommittee defined as required. Dr. Bernard Rubin asked whether there would be different modes of therapy depending on where you lived in Maryland. Williams said that the accessibility consideration might support the use of different therapies. If, for example, every person in the state was within an hour of an existing facility and optimum door-to-needle time should be less than two hours, or if you want diagnosis to catheterization lab time to be less than 2 hours, then additional resources may not be necessary if patients can get to existing programs within 1 hour.

Cummings agreed with Williams and noted that a number of the C-PORT projects now in operation functioned only on a 9 to 5 basis. If a patient goes to a hospital where the interventional team needs to be called in, then that team could go to a tertiary hospital if the outcomes prove to be better in that setting. Cummings noted the importance of considering resource issues given the expense of staffing catheterization labs on a 24/7 basis. He indicated that there were no hospitals in Baltimore that had a catheterization lab team in the hospital on a 24/7 basis. If you must call a team into the hospital during evening hours, it may be preferable to have patients go to a tertiary hospital.

- **What institutional resources are required for a primary angioplasty program?**
- **What are the program development requirements for a primary angioplasty program?**

Williams indicated, and the subcommittee agreed, that rules established for primary PCI institutional resources and program development should apply equally to hospitals with and without on-site cardiac surgery. He referred the subcommittee to Aversano's recommended criteria for primary PCI in hospitals without on-site cardiac surgery. These criteria are based on experience from the C-PORT project. Williams suggested that these criteria be discussed with the understanding that they would apply to hospitals with and without cardiac surgery. Seraphin asked whether the subcommittee agreed with the concept of primary angioplasty without on-site cardiac surgery. Williams recommended that the subcommittee review the criteria with the understanding that it was feasible to perform primary angioplasty without on-site cardiac surgery.

While he agreed that the number of MIs was important, Pollack said that the catheterization lab itself should have a high volume of routine, diagnostic procedures. Williams agreed with Pollack and suggested that catheterization lab volume be added to the list of criteria. He said that the original C-PORT criteria had used catheterization lab volumes as one of the criteria. With respect to the recommended volume of primary PCI cases, Williams noted that available data suggested that outcomes were better for programs performing 50 or more primary PCI cases. Friedman questioned whether 36 cases should be used as the recommended volume threshold rather than 50 cases. Williams said that the medical research data suggested that 36 cases were better than thrombolytic therapy but not better than 50 primary PCI cases. These are two separate questions. If you want to show superiority over thrombolytic therapy, you do not need to show the best result with primary angioplasty. On the other hand, if you want to show the best result then the data suggest 50 cases should be performed annually. Williams indicated that the standard should be based within reason on what is best. Friedman questioned whether setting the standard too high would have the impact of reducing access to care. Although physicians can refer open-heart surgery patients to high volume programs, with acute MI patients there is a need to provide care where the patient presents on a timely basis. While there may be circumstances where it is appropriate to have a lower standard, Pollack recommended that a high standard be used to avoid opening the door to substandard treatment. Williams suggested evaluating the impact of using 50 cases on access to primary PCI. Friedman noted that it was important to consider that in some areas of the state that outcomes would be improved using the lower threshold of 36 cases if the only alternative therapy was thrombolysis. Williams agreed and said that the minimum volume requirement should reflect access considerations. He suggested, and the subcommittee agreed, that under ideal circumstances better outcomes are achieved when 50 primary PCI cases are performed but that it should be noted that angioplasty is still superior to thrombolysis when 36 or more cases are performed and that should be incorporated in the equation when access to a program doing 50 cases does not exist. This approach would consider important regional differences in access to primary PCI services.

Rubin questioned the cost of maintaining a catheterization lab 24/7 to support 50 primary PCI cases annually. Gravino noted that the ACC/AHA guidelines suggest volumes as low as 36 primary PCI cases annually. Williams stated that this would be considered a IIB with the likelihood that it would become a IIA in the future. Seraphin said that it was important to clarify that the 50 cases referred to ST-segment elevation MI cases requiring primary PCI and not elective angioplasty or rescue angioplasty.

Williams asked whether the subcommittee believed that primary PCI programs should offer services on a 24/7 basis. Dr. Gravino said he felt that it was reasonable to expect the service to be offered on a 24/7 basis. He said that some hospitals with open heart surgery were not as organized in providing primary PCI services on a 24/7 basis as the community hospitals participating in C-PORT. Williams suggested that all hospitals be held to the same standard and he noted that in the Boston AMI program hospitals were monitored with the requirement that 80 percent of cases be performed within a certain timeframe. He suggested, and the subcommittee agreed, that a plan for monitoring the

implementation of any recommendations governing primary PCI be developed including the ability to make necessary changes if appropriate. After further discussion, it was the consensus of the subcommittee to recommend that primary PCI services be available on a 24/7 basis at hospitals with and without on-site cardiac surgery.

Williams asked the subcommittee for comments on the criteria recommending that the service be initiated only after a careful primary PCI development program that attends to setting of standards, training of staff, development of logistics and implementation of a formal quality and error management program; and the criteria recommending a formal agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care including emergency or elective cardiac surgery or PCI. The subcommittee agreed with these two recommendations.

With respect to patient transport, the draft suggested a formal agreement with an advanced cardiac life support EMS provider that guarantees arrival of the ambulance within 30 minutes of a request for patient transport. The subcommittee agreed with this recommendation with the amendment that the ambulance transport could be accomplished via air or ground.

Williams asked the subcommittee for comments on the recommendation to have adequate physician, nursing, and technical staff to provide services (catheterization lab and CCU). The subcommittee agreed with this requirement. He suggested, and the subcommittee agreed, that the commitment by hospital administration to support the program be a written commitment signed by the hospital president. It was the consensus of the subcommittee to incorporate the requirements as stated in items 8, 9, 10, and 11 of Aversano's document. Seraphin asked whether hospitals would apply for permission to perform primary angioplasty and respond to these criteria. Williams stated that the Commission would need to consider how institutions would respond to the subcommittee's recommendations. Seraphin suggested that the staff provide additional detail on recommendation 3 regarding staffing considerations. Williams recommended that the subcommittee use the requirements of the C-PORT training program.

Williams asked for comments on the physician criteria recommended in the Aversano document. In that document, it was recommended that physicians who perform primary PCI at hospitals without on-site cardiac surgery meet the ACC/AHA criteria for competency (greater than or equal to 75 cases per year); and, if newly out of fellowship (less than 3 years), operators should have a minimum of 25 cases proctored before being allowed to perform primary PCI alone. Seraphin asked how the physician criteria would be monitored. Williams suggested that responsibility for monitoring compliance rest with the director of the catheterization lab. After further discussion, it was agreed to revise item 2 under the physician criteria to state that operators should have experience in caring for at least 50 acute MI's in their fellowship.

- **Which patient groups are suitable for primary angioplasty in settings without on-site cardiac surgery?**

Williams asked for comments on the recommended patient criteria. The subcommittee agreed to recommend that patients with ST-segment elevation MI (or presumed new LBBB or ST-depression V1-V2 compatible with true posterior infarction) who are thrombolytic eligible or thrombolytic ineligible should be included. It was also agreed that patients with acute myocardial infarction in cardiogenic shock who the treating physician(s) believe may be harmed by transfer to a tertiary institution for treatment, either because the patient is too unstable or because the temporal delay will result in worse outcomes should be considered candidates for primary PCI. Williams asked for comments on the final criteria recommended for patients. This recommendation states that patients for whom the primary PCI system was not initially available, who received thrombolytic therapy which subsequently failed should be considered candidates for emergency PCI. These cases should constitute no more than 5 percent of all cases. He said that the concept is not to encourage lytic therapy and then angioplasty, but to encourage programs to commit first to angioplasty. Labs should do acute PCI and not delayed PCI. Williams noted that the Boston AMI program permits hospitals to have leeway on this issue. After further discussion, the consensus of the subcommittee was to revise the last sentence of item 3 to state no more than 10 percent (rather than 5 percent).

- **Is there a relationship between volume of primary angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?**

Williams noted that the subcommittee had already discussed the need to do 50 primary angioplasty cases. Another issue that the subcommittee should consider is the relationship between the volume of primary angioplasty cases and total angioplasty cases. He noted that while research suggested that 50 primary angioplasty cases is desirable it is also important to consider whether those cases were performed in a laboratory with high volumes of elective cases (more than 400 cases annually). Henry Meilman, M.D. expressed concern about the potential for stable, pain free AMI patients to undergo primary PCI because they present to a catheterization laboratory with a PCI team. Williams noted that the research data for this type of patient has changed over time. While data from earlier studies suggested this type of patient did not require an intervention, the more recent studies suggest that every MI patient should have a catheterization study and if there is a significant lesion it should be addressed. Williams noted that it was not necessarily a mortality benefit but rather a benefit from the standpoint of recurrent ischemia. Given this data, Williams said it was reasonable to perform PCI for this patient group and had become standard practice. Cummings agreed with Williams and said that to perform a catheterization study for this type of patient and then transfer when the PCI procedure could easily be completed would not be in the patient's best interest. Williams noted that this situation should occur infrequently because these patients have not received lytic therapy and so 80 percent will be totally occluded. The group of patients in question is those that are reperfused with lytic therapy

but there is a chance that the lesion would get better on its own and you could make it worse. In the absence of lytic therapy, Williams noted that the vast majority of these patients would be totally occluded.

- **What process and outcome measures should be used for on-going quality assessment?**

Williams asked staff to review the approaches to outcome measurement in the background materials and develop a proposal for review by the subcommittee.

Williams asked subcommittee members for additional comments on the proposed recommendations. Friedman asked about the impact of the Boston AMI plan on thrombolytic research. Williams said that it was possible to continue thrombolytic research if the patient could be taken to the catheterization laboratory. Seraphin noted that the Boston AMI plan (p. 11) recommended a door-to-balloon time of 120 minutes for 75 percent of patients. He asked whether PCI programs should have a turnaround time expectation. Williams said that door-to-balloon time was an important component of access. If it takes six hours, for example, between diagnosis and completing the procedure, then everyone could go anywhere to receive a given service. On the other hand, if the desired time is shorter then access becomes important. Williams said that this was an important issue and had a number of implications. He said that the door-to-balloon time should be an institutional criterion for programs with and without cardiac surgery. Cummings said that there were differences in how this type of data is tracked by programs and that it was important to measure uniformly. If it takes 30 minutes from the time that EMS comes until the patient gets to the emergency department of a small hospital and then it takes another 30 minutes to transfer to a PCI hospital, an hour can elapse without starting the intervention. Williams noted that this points out the need to use the 12-lead electrocardiogram to potentially reduce the time to diagnosis. Ideally, he said that a door-to-balloon time of less than 2 hours was desirable because data establish superior outcomes when compared to thrombolytic therapy when primary PCI is performed within 2 hours. In terms of access, Williams noted that areas outside, for example, a one-hour window to a tertiary PCI center would be where you would want to consider developing primary PCI capability. Cummings noted that this presented a wonderful opportunity to collect standard data on time and outcomes. Williams said that it was important to reflect the fact that beyond 120 minutes you lose superiority over primary PCI. He indicated that it was important for programs to be serious about the 120 minutes.

4. Discussion of Related Question Regarding Primary PCI

Williams asked for the subcommittee's thoughts on the development of a triage system for primary PCI. Rubin expressed concern about the potential to shift patients from a surgical to a non-surgical center with a triage system. If the statistics are good for surgical versus non-surgical centers, the Rubin questioned whether it would make a difference whether patients requiring primary PCI were referred. Williams noted the importance of considering access and determining regions of the state that were beyond

one hour from a PCI program. For patients outside this area, it may be appropriate to consider a new program. Williams pointed out that there is really no choice about where to go in this situation. Cummings said that if a patient were between a surgical hospital and a C-PORT hospital there would potentially be an option of where to take a patient. Meilman noted that the Inter-Hospital Transport Subcommittee had discussed this issue and thought that it would be appropriate to transport via the EMS system only to tertiary hospitals. Cummings noted the potential for time delays involved in inter-hospital transport of patients and said that his preference would be to focus first on getting to a tertiary hospital, then to a PCI hospital, and lastly to the nearest hospital. Meilman indicated that getting to the right hospital first was probably better.

Seraphin suggested careful analysis of available data to examine the need question. He said that there were approximately 10,000 AMI patients annually in Maryland. If approximately 20-25 percent of AMI patients were ST-elevation, which is the experience of the C-PORT hospitals, there would be only 5-7 primary PCI cases in the entire state daily that would require transport to a heart center. With the addition of Suburban Hospital, there will be 10 hospitals in Maryland with open-heart surgery programs. Seraphin said that it was not unreasonable to consider transporting patients who were already within one hour of a tertiary program. It is also important to consider that a large proportion of patients walk in to the emergency department.

Williams asked whether there was a consensus that the EMS system should expedite the transport of AMI patients to a PCI center, including those with and without on-site cardiac surgery. Because of the volume quality relationship, Williams said that it was important not to develop low volume angioplasty programs either with or without cardiac surgery. The subcommittee agreed with this statement. Karen Stair noted the difficulty of relying on private ambulances for inter-hospital transport in Western Maryland.

Williams said that staff would summarize this discussion and forward this document to each subcommittee member for review and comment.

5. Other Business

There was no other business discussed by the subcommittee

6. Adjournment

The subcommittee meeting adjourned at 5:00 p.m.

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care Interventional Cardiology Subcommittee

Monday, March 10, 2003
4160 Patterson Avenue
Baltimore, Maryland 21215

Subcommittee Members Present

David O. Williams, M.D., Chairman
George Bittar, M.D.
Sridhur Chatrathi, M.D.
Charles Cummings, M.D.
Michael Fiocco, M.D.
Scott Friedman, M.D.
Frank Gravino, M.D.
Bartley Griffith, M.D.
Roy Leiboff, M.D.
Keith M. Lindgren, M.D.
William Herzog, M.D.
Catherine L. Monge
Robin P. Newhouse, R.N.
Stephen H. Pollock, M.D.
Bernard Rubin, M.D.
Mitchell Schwartz, M.D.
Dominic Seraphin

Subcommittee Members Absent

Robert R. Bass, M.D.
James L. Field
Candice Fonke, R.N.
Steve B. Lowenthal, M.D.
Mark Midei, M.D.
James Porterfield, M.D.
Susheel Sharma, M.D.
Sidney C. Smith, M.D.
Karen Stair

Members of the Public Present

Vanessa Aburn, Union Memorial Hospital
Andrew Cohen
Sean P. Flanagan, Director, Government Relations, St. Joseph Medical Center
Gary Jones, Shore Health System
Sandra Mann, Johns Hopkins Medical Institutions
Richard McAlee, Southern Maryland Hospital Center
Martha Nathanson, LifeBridge Health
Lucy Shamash, SJMC

Members of Other Subcommittees

Henry Meilman, M.D.

Commission Staff Present

Barbara G. McLean
Pamela W. Barclay
Colleen Lates
Bridget Glazebrook
Susan Panek
Debbie Rajca
Dolores Sands

1. Call to Order

David O. Williams, M.D., Chairman of the Subcommittee, called the meeting to order at 4:00 p.m..

2. Approval of the Previous Minutes (January 27, 2003)

The minutes of the January 27, 2003 meeting were adopted as written.

3. Review and Discussion of Draft Statement on Acute ST-Segment Elevation Myocardial Infarction

Williams noted that the mailout package for the meeting included a draft statement on *Acute ST-Segment Elevation Myocardial Infarction* based on the subcommittee discussion at the January meeting. A summary of comments on the draft statement received from four individuals was distributed and reviewed by the subcommittee.

On page 1, paragraph 1 the subcommittee agreed to revise the third sentence to read: Under these exemption procedures, the former Maryland Health Resources Planning Commission approved a request from Tom Aversano, M.D. of the Johns Hopkins Medical Institutions to permit selected Maryland hospitals…..

The subcommittee asked staff to add language recommending field triage to a PCI center with cardiac surgical backup in the case where this option was available in an equivalent amount of time on page 2, Pre-Hospital Management of Acute ST-Segment Elevation Myocardial Infarction.

On page 2 (How do outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery compare with outcomes in hospitals with on-site surgery?), one commenter disagreed with the first sentence and stated that the subcommittee had not been given a copy of the Sanborn data. The commenter said that Wharton found one registry study by Weaver and co-workers that was published in 1993. There has been no recent study to support this position. The subcommittee agreed to change the first sentence to state: Some registry studies have suggested that programs without on-site cardiac surgery can safely and effectively provide primary angioplasty in a high-risk population and that outcomes might be similar to those reported from high volume surgical centers. In the last sentence of this paragraph, the subcommittee also agreed to delete the word "Accordingly".

In the first bullet under Institutional Resources (page 3), the subcommittee agreed to revise the requirement that all institutions perform a minimum of 500 diagnostic catheterization studies annually to use the C-PORT threshold criteria for AMI volumes.

The subcommittee agreed to revise the third bullet on page 4 to state as follows: create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes at a minimum the physician and nursing leadership of each care area

and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

The subcommittee agreed to revise the first bullet on Physician Resources (page 4) to state the physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MI's during their fellowship training or have 10 proctored cases before being allowed to perform primary PCI alone.

On page 5, Program Development Resources, the subcommittee recommended adding additional detail on the expectations for program development based on the C-PORT criteria.

Correct spelling error page 6, second bullet: Patients for whom the primary PCI system was not initially available, who received thrombolytic therapy that subsequently failed. ~~fails. ed~~.

On page 6, last paragraph, the subcommittee asked staff to add language regarding outcomes monitoring, using the C-PORT data elements, and collecting data for all patients including those transferred from a community hospital to a tertiary hospital.

Williams said that a revised draft of the statement on Acute ST-Segment Elevation Myocardial Infarction would be circulated to subcommittee members for review prior to the next meeting.

4. Review of Data and Discussion of Questions Posed in the Subcommittee Charge Regarding Elective Percutaneous Coronary Interventions (PCI)

Williams noted that the second phase of the subcommittee's discussions would focus on addressing the series of questions regarding elective angioplasty posed in the charge. He suggested that the subcommittee begin by discussing the status of access to elective angioplasty services under current policies. Stephen H. Pollack, M.D. observed that Maryland residents do not have difficulty obtaining access to elective angioplasty services. Scott Friedman, M.D. agreed with Pollack but noted that some patients have considerable distances to travel in order to access services. Roy Leiboff, M.D. indicated that distance considerations could negatively impact access, impose on patients and their families, and be extremely inconvenient. Pollack noted that access was not the same as convenience.

The second question posed in the subcommittee's charge regarding elective angioplasty concerns how the outcomes of elective angioplasty performed in hospitals without on-site cardiac surgery compare with the outcomes of elective angioplasty performed in hospitals with cardiac surgery. Unlike primary angioplasty, Williams noted that available data was sparse to address this question. William Herzog, M.D. noted that angioplasty without cardiac surgery backup was being done in North Carolina at a hospital about 90 miles from Duke University Hospital. Although data from this program may not have been published as yet, Herzog said that he would contact the program to determine what their experience has been. Williams noted that elective angioplasty without on-site cardiac surgery backup had been performed in Europe for many years. One of the biggest and busiest hospitals in Germany does not have on-site cardiac surgery. To some extent, Williams said that the question was not whether you could perform

angioplasty without on-site cardiac surgery backup but rather whether you should do it. Catherine L. Monge stated that Dr. Tom Aversano was developing a study design to test elective angioplasty in hospitals without on-site cardiac surgery backup.

Williams reviewed the third question posed in the subcommittee's charge which asks whether the Commission should consider a pilot project study to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients. Williams noted that this question was not asking whether a study should be done but whether the Commission should support and allow a pilot study of elective angioplasty in hospitals without on-site cardiac surgery.

Michael Fiocco, M.D. asked about the position of the American College of Cardiology regarding elective angioplasty in hospitals without cardiac surgery on-site. Charles Cummings, M.D. said that the American College of Cardiology considered elective angioplasty in hospitals without cardiac surgery to be a Class III indication meaning that there is general agreement that the procedure/treatment is not useful/effective, and in some cases might be harmful. Given the position of the American College of Cardiology, Pollack questioned how informed consent would be handled for patients participating in this type of study. While the risk of a significant complication during the procedure that would require on-site cardiac surgery might be small, Pollack noted that the only potential benefit for the patient would be convenience. Fiocco questioned why the legislature would consider enacting legislation that was contrary to the position of the ACC. Although the ACC position on primary angioplasty has changed, Cummings pointed out that when C-PORT was initiated in Maryland the ACC was not supporting primary angioplasty for patients with heart attacks in hospitals without on-site cardiac surgery. Before anything is done, someone must do it.

Williams noted that he was a member of the ACC Committee responsible for reviewing the guidelines governing angioplasty in hospitals without on-site cardiac surgery. Similar to the process being used by the Interventional Cardiology Subcommittee, Williams said that the ACC examined the published data and based the guidelines on established evidence. Like C-PORT, Williams said that the subcommittee was considering whether to consider an experiment or investigation involving clinical research to determine whether elective angioplasty in hospitals without on-site cardiac surgery was valuable or dangerous. He noted that in any clinical research there is some risk. Williams said that in his view elective angioplasty without on-site cardiac surgery would need to be done as a research project. As a research project, this would involve review by hospital IRBs, obtaining adequate funding, having a good study design and research methods, and a data coordinating center. Cummings questioned the ability to collect good data in this type of study. Additionally, he said that in the C-PORT study design an alternative therapy was being tested that many physicians felt would be clinically better for patients. In the case of elective angioplasty, no one thinks it is going to be better in community hospitals. On the contrary, Cummings noted that the concern was not harming patients. At best, one could hope for equivalence but it could turn out to be worse for patients.

Williams noted that he had talked with the physicians at the Mayo Clinic who have recently published data on about 200 consecutive elective angioplasty cases without on-site

cardiac surgery backup. The hospital was located about 85 miles from the Mayo Clinic in Minnesota. They took the number two cath lab physician and went to the outlying hospital and trained the staff and had all the staff come to Mayo Clinic. Following this training, they started to do selected cases under a protocol with informed consent. For cases that they did not want to do at the community hospital, the same physician would take back to Mayo. In other words, patients had the option of having the procedure at done at Mayo or having it done at the community hospital. Based on the small number of cases done to date, the results have been good. Williams provided subcommittee members with copies of the Mayo Clinic data and an accompanying editorial questioning the practice of performing elective angioplasty without on-site cardiac surgery backup. If elective angioplasty is done without on-site cardiac surgery backup, Williams said that it would need to be a research project. One difference as compared to C-PORT is the fact that C-PORT had the potential of saying that we might be able to do something since the clock was running with an acute MI and there might be a benefit to the patient. In the case of elective angioplasty, there is no clinical benefit. The benefit is convenience.

Given that Maryland is now considering adding more primary PCI centers without knowing whether the outcomes of primary angioplasty at community hospitals without on-site cardiac surgery programs are the same or better than outcomes at tertiary hospitals, Pollack questioned whether it was appropriate to undertake another study at this time. Before a research study of elective angioplasty is undertaken, Pollack said that we should have time to evaluate expanded primary angioplasty facilities. While it may be appropriate for Mayo Clinic to do this type of study, Bernard Rubin, M.D. questioned why the State would want to do this study. Barbara McLean pointed out that the State does not want to conduct this study. She noted that the Commission was seeking advice from the Advisory Committee on the question of whether the Commission should consider a proposal to conduct an elective angioplasty pilot study and, if so, what standards should be imposed. Rubin questioned why the State would want to consider this type of study before the scientific data were available.

Frank Gravino, M.D. pointed out that angioplasty was evolving and the fact that Maryland has experience with the C-PORT project suggests that a pilot study of elective angioplasty would be a good follow-up. Mitchell Schwartz, M.D. said that he believed it was a convenience issue and not a mortality issue. He said that the question is how far ahead of the curve does Maryland want to be. Given the angioplasty mortality is low, he suggested that Maryland consider being a leader in studying this issue because of our C-PORT experience. Alternatively, Maryland could wait until the ACC changes its classification of elective angioplasty from Class III to IIA. In the meantime, Schwartz noted that it was certainly possible that the legislature would take the decision away from the cardiology community. While Schwartz agreed with the concerns expressed by Pollack on the potential risks to the patients, he noted that a luncheon presentation by Tom Aversano, M.D. on elective angioplasty had indicated that the morbidity and mortality of delivering a baby at a birthing center was higher than elective angioplasty with a stent in a certain type of lesion. Schwartz said that the question will be answered and the issue is whether Maryland wants to participate in answering the question. Because of Maryland's C-PORT experience, Schwartz said that he felt it would be worthwhile to consider permitting a study of elective angioplasty in the state.

Leiboff said that in the future elective angioplasty without on-site cardiac surgery backup would likely become the mode of practice. This will occur sooner than we think based on when physicians feel comfortable with the ability to routinely handle complications. According to Leiboff, the real question is how motivated is the group, what is the interest, and are we the right people to study this question. If we have the appropriate people, interest, and resources and the desire to work on the question, then Leiboff argued that it should be permitted by the State of Maryland. The only question is how much interest and motivation is really there and where is it coming from—from the hospitals or the physicians. Leiboff said that in this instance the motivation should come from the physicians with the support of the hospitals. While he had the impression that a lot of hospitals want to have C-PORT, Leiboff said that the hospitals should not be the primary motivation in addressing this question. Rather the physicians who have the interest and desire to concentrate on answering these questions should be the primary drivers.

Schwartz said that it was important for the subcommittee to answer the question of whether the Commission should consider a pilot study of elective angioplasty without on-site cardiac surgery backup. Cummings said that the subcommittee should make the best recommendation possible and not anticipate that a study would be legislated. Sridhur Chatrathi, M.D. asked why the ACC considered elective angioplasty without on-site cardiac surgery backup as a Class III indication. Williams explained that the guidelines had been revised four times, with a fifth revision in process, and the process examines information. There are certain things in the guidelines that are intuitive. If something is wrong and there is no data to say it is right, then the ACC says it is wrong. Williams said that it was important to consider that people can require emergency coronary artery bypass surgery following an intervention and that if the guidelines are to say this is alright there should be data to say this is acceptable.

Chatrathi asked about patient selection. Williams said that the data from the Mayo Clinic addressed this issue and that it was possible, although expensive, to establish a rigorous patient selection process. Keith Lindgren, M.D. said that he was not opposed to a pilot project but this project was difficult to conceptualize. Under C-PORT there were at least strict criteria for the types of patients for entry in the study. With a statewide study of elective angioplasty, Lindgren expressed concern about the large number of interventionalists and centers that potentially would be reviewing cases and the difficulty in standardizing which patients would be selected. Although expensive, Lindgren said that the only way this could work acceptably would be if there were a central screening offices and a good scientific approach where all the images were digitally transmitted and reviewed. Williams pointed out that every hospital was not mandated to do this study and that perhaps only one hospital should study this issue. Williams also noted that physicians now doing angioplasty would be doing cases in any study and that it was not a question of new physicians.

Cummings expressed concern about the fact that the advantage of doing elective angioplasty in hospitals without on-site cardiac surgery backup was convenience while the downside was the potential for increased morbidity and mortality. Williams agreed with Cummings and said those are the issues that the study should answer. The study would need to be set up to say to the patient that you can have this procedure done here rather than where you normally would go at no excess risk of death. Williams said that while the purpose of the group

was not to design the study, it would be appropriate for the group to say that if something is submitted to the Commission there should be a mechanism for review of that study.

Pollack noted that the original C-PORT study was never really completed and that full funding was never received to complete the study as originally designed. Leiboff said that he felt it was important to have adequate funds to do this study and that it was a mistake that C-PORT did not receive adequate support. Although the state will not be funding this study, it is possible that NIH or another federal agency would provide necessary support. Leiboff stated his support for having the Commission consider a pilot study of elective angioplasty without on-site cardiac surgery backup. Cummings said that there should be consideration of studying whether it was safer to do primary angioplasty at a community hospital without on-site cardiac surgery versus transporting the patient to a high volume PCI center with cardiac surgery on-site. He argued that this question should be studied before continuing C-PORT.

Schwartz said that it financial issues were at play and that it was important to take finances off the table in discussing the merits of an elective angioplasty study. He supported the concept of having a subcommittee review any proposal to study elective angioplasty. In this manner, physicians and not hospital administrators would have the opportunity to review the appropriateness of the study design. Schwartz noted that hospital driven market share issues should be taken off the table and that the subcommittee should focus on what is best for the patient. He further commented that there were some scenarios outside of the Baltimore region that may make sense for elective angioplasty without on-site cardiac surgery backup.

In summary, Williams said that the subcommittee would be willing to review and critique a proposal for a pilot study and recommend that the state consider supporting a waiver for such a pilot study if the study were well designed. If the main benefit of elective angioplasty in hospitals without on-site cardiac surgery is patient convenience, Pollack questioned the benefit of conducting the study for patients. Friedman said that it was important to link elective and primary angioplasty for hospitals at a distance away from the large centers. According to Friedman, it is difficult to staff C-PORT hospitals when interventionalists are primarily located at elective angioplasty centers 90 minutes away. He said that the C-PORT hospitals located farthest away from Baltimore might have the greatest benefit for helping patients. Yet that is where the interventionalists need to work in order to do their 75 cases annually as required by ACC. In this regard, being able to do elective angioplasty at these hospitals is a practical solution, and not just a convenience, that facilitates performing primary angioplasty.

Rubin asked how the result would be interpreted if the study comparing on-site versus no on-site cardiac surgery backup for elective angioplasty finds no statistical difference. If the only value is convenience and there is no clear indication that it is inferior, does that still mean the two are equal. Williams agreed that the implication would in fact be that the two are equal. Chatrathi noted that the state did permit diagnostic catheterization studies to be performed in hospitals without on-site cardiac surgery backup. Williams noted that in the case of diagnostic catheterization studies, unlike elective angioplasty, there was no recommendation from a professional body that required immediate cardiac surgical backup. He said that at one time there were no outpatient diagnostic catheterizations and when physicians noted that it would be convenient to send patients home this practice was eventually determined to work.

Dominic Seraphin noted that in the absence of evidence supporting elective angioplasty without on-site cardiac surgery backup it might be preferable to examine the need for a cardiac surgery program at hospitals outside the metropolitan areas to backup the angioplasty programs. Williams noted that even if Maryland does nothing regarding the study of elective angioplasty that the answer will evolve over time. The question is does Maryland want to be involved? Cummings agreed with Williams and said that the subcommittee had the right goals and should be involved in deciding how this type of study would be accomplished. While the practice of elective angioplasty without on-site cardiac surgical support is likely to grow, Cummings said that he felt it was important to be done in a controlled fashion.

Bartley Griffith, M.D. asked about the impact of increasing cardiac surgical sites to support primary angioplasty programs. Because Maryland regulates the number of cardiac surgery programs, the growth in angioplasty is driving the state toward legislation that requires either increasing surgical programs or letting hospitals perform elective angioplasty without cardiac surgical backup on-site. Pollack said that the Commission should focus on what is best for patients and not on developing a political compromise. Barbara McLean explained the process that would be used by the Commission. The recommendations from the Interventional Cardiology Subcommittee would go to the Steering Committee and then to the Commission for action. The Commission does not require legislative action to consider supporting the pilot project to study elective angioplasty. Pollack said that the subcommittee should take a position opposing bills regarding elective angioplasty that do not go through the proper process established by the Commission. Cummings said that the study design would be critical to ensure that the proper questions are addressed.

Although the remaining questions in the subcommittee charge regarding elective angioplasty assume that a pilot study would be conducted, Williams asked the subcommittee for comments on the volume-quality relationship for elective angioplasty. He noted that available data suggests better outcomes for programs performing a minimum of 400 elective angioplasty cases. In terms of the question regarding groups of patients suitable for inclusion in a pilot study, Williams said that this would be a component of the pilot research study review process. Lindgren said that he felt it was important for the subcommittee to say that it is wrong to uncouple angioplasty and on-site cardiac surgery without data. While the data is not yet available, Lindgren said that the subcommittee should support reviewing additional data from a pilot study or other research and reconsidering this policy. Fiocco agreed with Lindgren and said that the reason to further examine angioplasty without on-site cardiac surgery is for no other benefit than the convenience of patients and perhaps families and physicians. Williams noted that there was no clinical benefit as yet in performing angioplasty without on-site cardiac surgery support.

Leiboff said that he thought a lot of Southern Maryland patients would participate in the study. Herzog agreed with Leibhoff and said that patients would be willing to accept a slightly higher risk. Cummings said that it was important to have the expertise of the subcommittee leading this process. Lindgren noted that Maryland had done the C-PORT study and had high standards and could build on this experience. Robin Newhouse, R.N. noted that C-PORT was about clinical outcomes and a study of elective angioplasty would potentially be about the

organizational infrastructure. She expressed concern about the ability to seek objective data when some hospitals are lobbying for the ability to perform angioplasty without on-site cardiac surgery backup. Williams explained that a third party and not an individual hospital would generate the study and probably involve multiple states and be organized privately with clinical end points. He went on to say that the study would likely be a registry with larger numbers of patients than the Mayo Clinic Study so that you would have large enough event rates to show safety. Hospitals would participate as potential clinical sites of the study and enroll patients. Newhouse asked about the timing of the policy decision. Williams said that the study might take 1-2 years to complete and that the policy should not change until the data has been examined.

Dominic Serphin noted that HSCRC would be concerned about the significant duplication of costs involved in establishing multiple centers and the potential for cherry picking lower risk patients to centers without cardiac surgery leaving higher risk patients dumped to the heart centers that under the current reimbursement system would hurt those hospitals. Williams said that it was appropriate for the study to look at the easiest cases and that the study would not be comparing all elective cases in Maryland done at community hospitals versus all tough cases done at tertiary hospitals. Williams noted that this was analogous to the impact of developing freestanding ambulatory surgery centers on existing hospital-based outpatient surgery capacity. If you think this is legitimate from a clinical viewpoint, then it may be appropriate to consider changes to the rate setting system rules. Seraphin said this would be appropriate to reflect in the subcommittee recommendations.

5. Other Business

There was no other business discussed by the subcommittee

6. Adjournment

The subcommittee meeting adjourned at 5:55 p.m.

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care Interventional Cardiology Subcommittee

Monday, April 14, 2003
4160 Patterson Avenue
Baltimore, Maryland 21215

Subcommittee Members Present
David O. Williams, M.D., Chairman
James Scheuer, M.D., Chairman of the Steering Committee
Robert R. Bass, M.D.
Charles Cummings, M.D.
Michael Fiocco, M.D.
Scott Friedman, M.D.
Bartley Griffith, M.D.
William Herzog, M.D.
Keith M. Lindgren, M.D.
Steve B. Lowenthal, M.D.
Mark Midei, M.D.
Catherine L. Monge
Robin P. Newhouse, R.N.
Bernard Rubin, M.D.
Dominic Seraphin
Karen Stair, R.N.

Subcommittee Members Absent
George Bittar, M.D.
Sridhur Chatrathi, M.D.
James L. Field, DBA
Candice Fonke, R.N.
Frank Gravino, M.D.
Roy Leiboff, M.D.
Stephen H. Pollock, M.D.
James K. Porterfield, M.D.
Mitchell Schwartz, M.D.
Susheel Sharma, M.D.
Sidney C. Smith, Jr., M.D.

Members of the Public Present
Vanessa Aburn, Union Memorial Hospital
Paul Blackwood, Dimensions Health System
Clarence Brewton, MedStar Health
Andrew Cohen
Sean P. Flanagan, St. Joseph Medical Center
Gary Jones, Shore Health System
Sandra Mann, Johns Hopkins Medical Institutions
Vanessa Purnell, MedStar Health
Jack Tranter, Gallagher, Evelius & Jones

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Bridget Glazebrook
Colleen Lates
Susan Panek
Debbie Rajca
Dolores Sands
Suellen Wideman, Assistant Attorney General, Commission Counsel

1. Call to Order

David O. Williams, M.D., Chairman of the Subcommittee, called the meeting to order at 4:05 p.m. Dr. Williams welcomed James Scheuer, M.D., Chairman of the Steering Committee, and asked the members of the subcommittee to introduce themselves.

2. Approval of the Previous Minutes (March 10, 2003)

The minutes of the March 10, 2003 meeting were adopted as written.

3. Review and Final Approval of Statement on Acute ST-Segment Elevation Myocardial Infarction: Recommendations of the Interventional Cardiology Subcommittee (Revised Draft)

Dr. Williams said that he will present a summary of the subcommittee's recommendations to the Steering Committee after this meeting. He reported that the changes recommended at the last meeting had been incorporated into the revised draft, which was included in this meeting's package. He then presented several other suggested changes. Firstly, under Institutional Resources, number three (page three) of the current draft, in regard to ideal door-to-balloon time, Dr. Williams suggested the statement should read: All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes after patient arrival (i.e., door-to-balloon time of $\leq$ 120 minutes) for 80 percent of appropriate patients. The rationale for the revision was to emphasize that the sooner PCI is provided, the better. The subcommittee members approved the change with no discussion and no objections.

Secondly, Dr. Williams recommended changing the wording under Physician Resources, number one (page five) to read: Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total cases per year. The revised statement better reflects the original wording and meaning in the ACC/AHA guidelines.

Thirdly, Dr. Williams suggested moving the first recommendation under Institutional Resources (page three): "All institutions should demonstrate that they have a minimum of 80 ST-segment elevation MIs annually." The recommendation should be located under Initiation of a New PCI Program (page five). Scott Friedman, M.D. questioned why the volume of 80 was selected, when the minimum standard of 50 to 75 cases is used in the guidelines. Dr. Williams responded that the number of MIs must be a higher number than the minimum PCI procedures; otherwise, every case must undergo PCI in order for the individual or center (36 primary PCI procedures/year) to meet the standard. Dr. Scheuer pointed out that the individual operator needs a minimum number of patients undergoing PCI less than 12 hours from the onset of symptoms, although some other patients may receive angioplasty beyond 12 hours. Further, Dr. Williams said the volume of 80 ST-segment elevation MIs was used as a surrogate for experienced personnel. He also noted that C-PORT used that measure, in part, as a criterion. Part of C-PORT's success was due to the criteria it used for hospital and patient participation. Dr. Williams noted that there is no other data available to support deviating from C-PORT's criterion.

Bernard Rubin, M.D. supported the recommendation to clarify the door-to-balloon time as "as soon as possible" or within 120 minutes, but wanted to also clarify that the time requirement stood for 80 percent of appropriate patients. Dr. Williams responded that there was no change except the timing. Charles Cummings, M.D. inquired what a program should do if the personnel anticipated that it would take longer than 120 minutes for door-to-balloon time, i.e., transfer the patient to another facility, or administer thrombolytics. Dr. Williams replied that the physician should use his or her best judgment, adding that it was up to the discretion of the physician to respond in the best interest for the patient on an individual level.

Dr. Williams asked whether the subcommittee members accepted the report with the non-substantive changes discussed. The motion to accept the report was made by Dr. Cummings, and seconded by Dr. Rubin. The members present were in unanimous agreement on the report.

4. Review and Discussion of Draft Statement on Elective Percutaneous Coronary Interventions (PCI): Recommendations of the Interventional Cardiology Subcommittee

Dr. Williams commenced the review of the elective PCI report by saying that the draft had been distributed last week. He presented the subcommittee chairman's suggested changes, beginning with the deletion of a redundant sentence on page two, paragraph two: As experience with PCI has increased over the past decade, it has been recognized that it is possible to perform elective procedures without on-site surgical backup. On the same page, paragraph three, Dr. Williams recommended a change to the last sentence: There has been no clinical trial directly comparing the outcomes of elective PCI performed in hospitals with on-site cardiac surgery with the outcomes of elective PCI performed in hospitals without on-site cardiac surgery. He also suggested that further explanation should be added: Moreover, methods for identifying those patients who might be more suitable for elective PCI without on-site surgical backup have not been described or validated. Dr. Williams noted that a review of over 6,000 consecutive patient records within a registry for 16 centers did not reveal a pattern of which patients are best suited to such care. There was not an obvious low-risk group with regard to selecting patients who did not need surgery.

Dr. Williams suggested that the last paragraph on page three be revised to reflect that each hospital needs to decide whether to be involved in the process for a waiver: A hospital wishing to participate in such a research proposal can apply for this waiver. That is, involvement would be on a voluntary basis.

Steve B. Lowenthal, M.D. inquired about the purpose of the information included on pages 4-7 about the volume-quality relationship. Dr. Williams said the section is in response to a question in the charge to the subcommittee regarding elective angioplasty, and that it is included for background purposes. Dr. Rubin thought its inclusion suggested that a hospital requesting a waiver for the pilot project must demonstrate that it was capable of producing a minimum volume of 400 cases. Dr. Lowenthal and Catherine L. Monge agreed with this interpretation. Dr. Williams stated that the minimum of 400 cases was not a criterion for entry in the pilot research project regarding elective angioplasty. Dr. Friedman noted that the text of the ACC/AHA guidelines for PCI (2001) lists minimal institutional performance activity of 200

interventions per year with the ideal minimum of 400 interventions per year, and that volume recommendations differ based on Class (risk assessment and expected efficacy in the context of the strength of current knowledge). Class I is PCI done by operators with acceptable volume (≥ 75) at high-volume centers (> 400). Class IIa is PCI done by operators with acceptable volume (≥ 75) at low-volume centers (200 to 400). Dr. Williams agreed that additional text using that wording to get the correct sentiment would be beneficial to the current report.

Dr. Williams inquired why the issue of volume was introduced into the report on elective PCI. Pamela Barclay responded that there is not a specific connection to the research proposal. She said that the intent was to obtain advice on a minimum volume standard for elective angioplasty in the State Health Plan. Dr. Williams recommended that the current document be separated into two documents to avoid confusion. Ms. Barclay referred to item four on page four as the criteria addressing participation in the pilot research project.

Dr. Rubin wanted to know, if minimum standards exist, how the Commission could allow a waiver if a hospital has no capabilities of meeting those standards. Dr. Lowenthal said that those volumes will be a major component after the pilot project. Dominic Seraphin argued that it was reasonable that a hospital should be able demonstrate that it has the potential to do 200-400 cases annually before provided a waiver. Dr. Cummings said that it will be hard for a hospital, particularly in Baltimore, to demonstrate that it has the minimum number of patients. Dr. Williams felt that such discussions were more relevant to the actual design of the pilot project, which was not the charge of this subcommittee.

Mark Midei, M.D. inquired if the subcommittee had decided that the merits of a pilot project were worth pursuing. Dr. Williams responded that the subcommittee decided at another meeting that if a rigorous, well-designed trial was available and presented, the MHCC should consider providing waivers. Dr. Cummings inquired if there would be a committee to review the proposal. Michael Fiocco, M.D. added that it is essential that the pilot project makes it clear that there is no benefit to the patient, except for convenience; in fact, it may be of detriment. Dr. Williams said that the only other potential asset (in addition to convenience) is a more robust program that helps retain the interventionalist. Dr. Midei said that page three should indicate that the end points are clearly designed to show benefit to the patient. Dr. Williams agreed that the question to be answered is in regard to the safety of the procedure being performed without on-site surgical backup.

Dr. Cummings suggested that a simple prospective study might assist in determining the need for the pilot project being discussed. He suggested that for the next 10,000 consecutive angioplasty procedures, physicians nationwide could try to predict which patients would not be harmed. This would involve zero-risk to the patient, would be inexpensive, and would answer the question of whether this is unsafe. Dr. Williams noted that the ACC Registry is collecting data and would be useful in a predictive study. Dr. Rubin noted that community hospitals, with no backup, might not have the same experience to make the appropriate decision, as hospitals experienced in elective PCI and open heart surgery. Dr. Midei said that in Maryland, volumes were centralized, resulting in quality that was probably better than the rest of the country. He was concerned that the subcommittee was recommending a pilot project that would endanger Maryland's centralization and dilute the numbers, which he equated to reducing quality. He

stated that he felt the minimum standards of the ACC/AHA were abysmally low and were arrived at to keep peace within the ACC. Dr. Williams responded that the minimum standards in the ACC/AHA guidelines were data-driven.

Referring to page four, number four, Dr. Rubin expressed reservations about the proposal and suggested adding to the last sentence: The subcommittee also recommends that the Commission appoint an advisory committee to review and provide advice on any research proposal submitted to the Commission to study elective angioplasty without on-site cardiac surgery backup, and to decide how to act based on the results of the study. Dr. Lowenthal asked whether a committee would design the study. Dr. Williams said that a hospital would submit the proposal through its IRB, then to the committee. Dr. Lowenthal asked about a body to approve the design; provide ongoing monitoring (e.g., quarterly); and, after a period, perform retrospective analysis and draw conclusions. Dr. Williams said that the Advisory Committee to MHCC, or an offshoot of the Advisory Committee, would have a role in overseeing the pilot. Dr. Lowenthal suggested including a timetable to initiate as well as complete the study.

Mr. Seraphin stated that the lack of a clinical benefit for patients needed to be stated more firmly (on page three, last paragraph): The Interventional Cardiology Subcommittee believes there is no clinical benefit; nevertheless, the Interventional Cardiology Subcommittee believes that it would be appropriate for the Commission to consider supporting a waiver for a well-designed, peer reviewed research proposal to study elective PCI without on-site cardiac surgery. Dr. Fiocco agreed that the point (i.e., for the convenience of patients and the hospital) needed to be stressed and mentioned more than once in the document. Keith M. Lindgren, M.D. noted that the minutes from the March 10, 2003 meeting include a strong statement and document the discussion held previously about the concern of the lack of clinical benefit to the patient (pages 8-9). Dr. Williams agreed to work on the wording.

Mr. Seraphin also expressed the need to add a further criterion to item four (page four), the pilot project design, to include: (8) minimum volume standards for the practitioner and institution. Dr. Lowenthal said that the proposal could include a generic statement regarding volumes. Dr. Williams responded that item 5 addresses volumes for elective angioplasty.

Lastly, Mr. Seraphin suggested that the design needed to include an analysis of the financial impact on existing providers and the cost-benefit. He suggested that the Health Services Cost Review Commission (HSCRC) should hold harmless other hospitals currently performing elective angioplasty. Other members questioned if the financial impact analysis was the responsibility of the investigators, rather than a criterion for the MHCC to address in Certificate of Need reviews. Dr. Williams stated he was unsure how or why a clinical trial in a hospital would need to consider impact on some other hospital. Barbara McLean agreed that the two issues needed to be separated. Mr. Seraphin was concerned that if, for example, five pilot hospitals performed 400 elective angioplasty cases each, the total of 2,000 cases could have a significant impact on cases performed by current open heart surgery hospitals in the area.

Dr. Cummings stated that, unlike C-PORT I, the pilot project would not be looking at clinical benefits, and he said that it was important to consider costs, for example, new cath labs, staff, and equipment. The citizens must pay for convenience. Dr. Rubin said that financial

impact had nothing to do with the clinical study itself. Dr. Lowenthal noted that HSCRC theoretically pays the same for a procedure no matter where it is performed (whether there are eight access points or three). However, he said that the pilot project may have other possible benefits, such as improved access. Dr. Williams stated that the goal of the study would be to investigate safety, not feasibility. Mr. Seraphin noted that the safety of the system cannot be separated from that of the patient. Dr. Scheuer suggested that James L. Field, Director, Cardiovascular Roundtable, Advisory Board Company, or a similar organization, could model various changes in interventional practice and the shifts of patients in the health system as a precursor to the research project. Dr. Williams said that the effort could happen concurrently or beforehand. He said that he would add further text about the implications of elective angioplasty being performed in hospitals without on-site backup surgery, additional considerations given the possibility of indications that the procedure is not only feasible, but also safe.

5. Other Business

Dr. Williams drew the members' attention to the March *Circulation* journal articles[18], which had been provided. Dr. Cummings commented that one article reviewed the C-PORT trial and noted that the inclusion of a third randomized arm, that is, transport to a high-volume center for PCI, would have been a very useful comparator for on-site community hospital PCI. Dr. Cummings noted that Maryland still has an opportunity to do a transport arm to answer the question: Is it better to be transferred to a high-volume hospital, or stay in a community hospital? Dr. Williams noted that Spain is currently doing a similar study now. The Danish trials in Acute Myocardial Infarction (DANAMI) did not examine that issue.

Mr. Seraphin questioned if it was possible to have a joint meeting with the Inter-Hospital Transport Subcommittee. Dr. Williams responded that the issues being raised are research questions and are not covered in the current charge. Dr. Cummings pointed out that it is the charge of this subcommittee to recommend the continuation of C-PORT, and it could recommend that C-PORT investigate transport. Dr. Fiocco questioned where a study that demonstrated that it was better to transfer a patient to a high-volume facility with on-site surgical backup, compared to C-PORT, would lead Maryland. Dr. Cummings said that many heart attacks happen in the morning, when a team is already in the hospital. He raised the question of whether transferring the patient would always be better, considering such problems as traffic and weather. Dr. Williams noted that it might be difficult to take away C-PORT from the hospitals, in the absence of a definitive study showing that people are being harmed. Strong volume standards help to provide assurance about the care.

Mr. Seraphin asked if the subcommittee should recommend that MIEMSS complete a transport study. Dr. Lowenthal inquired if the Inter-Hospital Transport Subcommittee had addressed any of these issues. Dr. Scheuer reported that the Inter-Hospital Transport Subcommittee had not looked at recommending a research project, but had focused its discussion

[18] Eric J. Topol, M.D.; Dean J. Kereiakes, M.D., Regionalization of Care for Acute Ischemic Heart Disease: A Call for Specialized Centers. Circulation 2003; 107: 1463-1466.
Robert M. Califf, M.D.; David P. Faxon, M.D., Need for Centers to Care for Patients With Acute Coronary Syndromes. Circulation 2003; 107: 1467-1470.
James T. Willerson, M.D. Editor's Commentary: Centers of Excellence. Circulation 2003; 107: 1471-1472.

on 12-lead ECGs, development of inter-hospital transfer guidelines, and streamlining the call for an ambulance. Dr. Williams stated that he would add to the Acute ST-Segment Elevation Myocardial Infarction Report that an alternative strategy has not been evaluated and there is merit to investigating transport as a part of C-PORT.

Dr. Friedman offered the perspective of a transferring facility. He raised the issue of how the analysis of subgroups of patients and the results of a trial affect the person making a decision in the emergency department as to whether transferring a patient increases the risk. He added that a hospital cannot plan based on subgroup analysis; it must implement the whole program.

Dr. Williams said that this discussion ends the charge to the subcommittee. He said he would modify the document as discussed and send it out to members for their comments. The subcommittee will meet again, if necessary.

Dr. Williams finished the meeting by thanking all subcommittee members for their participation. He expressed his pleasure in working with a heterogeneous group with many constituents and points. Dr. Scheuer added that the work and effort of this scholarly committee was appreciated by the Steering Committee.

6. Adjournment

The subcommittee meeting adjourned at 5:15 p.m.

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